As filed with the Securities and Exchange Commission on September 17, 2014

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

HedgePath Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	2834	30-0793665
(State or jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(IRS Employer Identification No.)

324 S. Hyde Park Avenue, Ste. 350
Tampa, Florida 33606
(813) 864-2559
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Mr. Nicholas J. Virca
President and Chief Executive Officer
324 S. Hyde Park Avenue, Ste. 350
Tampa, Florida 33606
Phone: (813) 864-2559
Fax: (813) 258-6912
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Barry I. Grossman, Esq.
Lawrence A. Rosenbloom, Esq.
Ellenoff Grossman &Schole LLP
1345 Avenue of the Americas
New York, New York 10105
Phone: (212) 370-1300
Fax: (212) 370-7889

Megan N. Gates, Esq.
Garrett M. Winslow, Esq.
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111
Phone: (617) 542-6000
Fax: (617) 542-2241

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If delivery of the Prospectus is expected to be made pursuant to Rule 434, check the following box. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To be Registered(1)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee
Common stock, par value $0.0001 per share	$5,000,000	$644.00
Placement agent warrant(3)	—	
Shares of common stock, par value $0.0001 per share, underlying placement agent warrant(4)	$220,000	$28.34
TOTAL	$5,220,000	$672.34

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended, referred to as the Securities Act, the number of shares of common stock registered hereby shall also include an indeterminate number of additional shares of common stock issuable as a result of stock splits, stock dividends, recapitalizations, reorganizations or similar transactions.
(2) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(o) under the Securities Act.
(3) No registration fee is required pursuant to Rule 457(g) under the Securities Act.
(4) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act. The placement agent warrant is exercisable at a per share exercise price equal to 110% of the public offering price. As estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act, the proposed maximum aggregate offering price of the placement agent warrant is $220,000 (which is equal to 110% of $200,000 (4% of $5,000,000).

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Preliminary Prospectus **Subject to Completion, dated September 17, 2014**

Shares

Common Stock

We are offering shares of our common stock on a "best efforts" basis. We are not required to sell any specific dollar amount or number of shares. Our common stock is listed for quotation on the Over-the-counter bulletin board (or OTCBB) and the OTCQB marketplace operated by the OTC Markets Group, Inc., under the symbol "HPPI". On September 16, 2014, the last reported market price of our shares of common stock was $0.15.

Investing in our common stock involves substantial risk. In reviewing this prospectus, you should carefully consider the matters described under the heading "Risk Factors" beginning on page 7.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Offering price per share of common stock	$	$
Placement agent's fees(1)	$	$
Proceeds, before expenses, to us	$	$

(1) Does not include a non-accountable expense allowance in the amount of up to $125,000, payable to H.C. Wainwright & Co., LLC, the placement agent for this offering, and warrants issuable to H.C. Wainwright & Co., LLC, to purchase the number of shares of common stock equal to up to 4% of the shares of common stock sold in this offering. For further information, see "Plan of Distribution."

There is no minimum amount of securities that must be sold as a condition to closing this offering. We have retained H.C. Wainwright & Co., LLC as our placement agent to use its commercially reasonable best efforts to solicit offers to purchase our securities in this offering. We intend to enter into a placement agent agreement with H.C. Wainwright & Co., LLC relating to the shares of common stock offered by this prospectus. H.C. Wainwright & Co., LLC is not required to sell any specific number or dollar amount of shares but will use its commercially reasonable best efforts to sell the shares of common stock being offered. We have agreed to indemnify H.C. Wainwright & Co., LLC against certain liabilities, including liabilities under the Securities Act of 1933, as amended (which we refer to herein as the Securities Act), and to contribute to payments that H.C. Wainwright & Co., LLC may be required to make in respect thereof. In consideration for its services, in addition to the cash fees set forth in the table above, we have agreed to issue to H.C. Wainwright & Co., LLC or its designee five-year warrants to purchase up to an aggregate of shares of our common stock at an exercise price of $ per share (equal to 110% of the offering price per share).

We expect that delivery of the securities being offered pursuant to this prospectus will be made to purchasers on or about , 2014. We may decide to terminate the offering at any time without further notice to investors. Pursuant to an escrow agreement among us, H.C. Wainwright & Co., LLC and American Stock Transfer & Trust Company, as escrow agent, the funds received in payment for the shares sold in this offering will be wired to a non-interest bearing escrow account and held until we and H.C. Wainwright & Co., LLC notify the escrow agent that this offering has closed.

Placement Agent

H.C. Wainwright & Co., LLC

The date of this prospectus is , 2014

Table of Contents

TABLE OF CONTENTS

Please read this prospectus carefully. It describes our business, our financial condition and our results of operations. We have prepared this prospectus so that you will have the information necessary to make an informed investment decision. You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with any information or to make any representations about us, the securities being offered pursuant to this prospectus or any other matter discussed in this prospectus, other than the information and representations contained in this prospectus. If any other information or representation is given or made, such information or representation may not be relied upon as having been authorized by us.

The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock. Neither the delivery of this prospectus nor any distribution of securities in accordance with this prospectus shall, under any circumstances, imply that there has been no change in our affairs since the date of this prospectus. This prospectus will be updated and made available for delivery to the extent required by the federal securities laws.

This prospectus includes estimates, statistics and other industry data that we obtained from industry publications, research, surveys and studies conducted by third parties and publicly available information. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. This prospectus also includes data based on our own internal estimates. We caution you not to give undue weight to such projections, assumptions and estimates.

For investors outside the United States: Neither we nor the placement agent have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. To understand this offering fully, you should read the entire prospectus carefully, including the "Risk Factors" section, the financial statements and the notes to the financial statements. Unless the context otherwise requires, references contained in this prospectus to the "Company," "we," "us," or "our" refers to HedgePath Pharmaceuticals, Inc., a Delaware corporation.

Overview

We are a biopharmaceutical company that is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers. Our preliminary focus is on the development of therapies for skin, prostate and lung cancers in the U.S. market. Our proposed therapy is based upon the use of a patented formulation of the currently marketed anti-fungal drug itraconazole.

Following a meeting between our management and representatives of the United States Food and Drug Administration (or FDA) in August 2014, we anticipate submitting an Investigational New Drug (IND) application in September 2014 for the use of our product candidate to treat basal cell carcinoma in patients with Gorlin Syndrome, a genetic disease also known as basal cell carcinoma nevus syndrome, which, among other conditions, causes the chronic formation of basal cell tumors.

We have developed, licensed and are seeking to acquire and/or license, intellectual property and know-how related to the treatment of cancer patients using itraconazole and have applied for patents to cover our inventions. We have exclusive rights in the U.S. to develop and to commercialize a specially formulated, patented version of itraconazole, known as SUBA™-Itraconazole Capsules , for the treatment of human cancer via oral administration. SUBA-Itraconazole was developed and is licensed to us by our manufacturing partner and significant shareholder Mayne Pharma Ventures Pty Ltd. and its affiliates (which we refer to herein as Mayne Pharma) under a Supply and License Agreement, originally dated September 3, 2013 and most recently amended and restated on June 24, 2014. We refer to this agreement herein as the Supply and License Agreement. Mayne Pharma is an Australian specialty pharmaceutical company that develops and manufactures branded and generic products, which it distributes directly or through distribution partners and also provides contract development and manufacturing services. In addition to being our licensor and supply partner, under the Supply and License Agreement and related agreements, Mayne Pharma holds a significant minority equity stake in our company and holds important rights with respect to our company, such as the right to appoint a member to our Board of Directors. See "Business—Manufacturing and Product Supply and Relationship with Mayne Pharma" and "Certain Relationships and Related Party Transactions" for a further description of Mayne Pharma's rights.

"SUBA™ technology" (which stands for "super bioavailability") is designed to improve the bioavailability of orally administered drugs that are poorly soluble. In studies conducted by Mayne Pharma relating to SUBA-Itraconazole's anti-fungal application, SUBA-Itraconazole has demonstrated improved absorption and significantly reduced variability compared to the branded and generic forms of itraconazole in human studies. We believe this technology is well-suited for the exploration of the potential anti-cancer effects of itraconazole.

Based on existing scientific (including in vitro, animal and human studies)data, we believe that itraconazole affects the Hedgehog signaling pathway in cells, a major regulator of many fundamental cellular processes, which will in turn impact the development and growth of certain cancers. Itraconazole appears to have notable anti-cancer effects by one or more independent or synergistic mechanisms, some of which are not clearly understood and continue to be the subject of on-going research. These anti-cancer effects have been demonstrated in various animal models and subsequently in human studies conducted by clinicians and investigators at leading research institutions over the last few years, all of which are the basis of our interest in the clinical development of itraconazole for treatment of human cancers.

Our regulatory strategy is driven by the so called 505(b)(2) regulatory pathway, under which a drug (in our case, itraconazole) that has already been approved for use in humans in the United States by the United States Food and Drug Administration (or FDA) is developed for one or more new medical indications (in our case, as an anti-cancer agent). Due to the history of safe and efficacious use of itraconazole in humans for anti-fungal applications, we believe the 505(b)(2) pathway will be available to us, which may create the potential for significantly reducing the risk and time to achieve FDA approval of our cancer therapy.

Table of Contents

We believe we have the opportunity to clinically progress and, if regulatory approvals are secured, commercialize SUBA-Itraconazole oral capsules as an anti-cancer therapy in the United States based on the following:

- We expect to be able move directly into Phase II trials based upon the track record of long-term, safe and effective use of itraconazole for treatment of human fungal infections;
- Agreement by FDA that we may cross-reference Mayne Pharma's IND to support our plan to advance SUBA-Itraconazole into Phase II trials;
- Existing Phase II human data for skin, lung and prostate cancers have already demonstrated initial efficacy of itraconazole as an anti-cancer therapy;
- There are large and growing available markets for our proposed anti-cancer indications;
- We may qualify for one or more expedited review and approval programs by the FDA;
- If approved, our therapies could be offered at reduced cost compared to current treatments;
- We have exclusive rights to develop and commercialize SUBA-Itraconazole in the U.S. through Mayne Pharma for a patented, more bioavailable formulation of itraconazole which we believe will allow us to treat cancer patients with less toxicity and greater consistency than the conventional formulations;
- We have secured a cGMP (clinical good manufacturing practice) supply of product for clinical trials and eventual commercialization in the U.S. under exclusivity through Mayne Pharma and
- Our management and consulting team bring extensive, prior experience in the clinical development of oncology therapeutics.

Our Potential Market

The following table depicts our current estimate of the total available market opportunity for our proposed anti-cancer therapies based upon independent market research, scientific and industry publications and management's knowledge of the U.S. oncology market. Our estimates (including estimated product pricing) are based on current assumptions and are subject to change.

HedgePath Pharmaceuticals, Inc. – Summary U.S. Market Opportunity

Cancer	Therapy Indication	Potential for SUBA-Itraconazole	Target Patient Population	U.S. Total Available Market
Skin(1)	Patients with BCC (basal cell carcinoma) lesions First indication: BCC tumors in Gorlin Syndrome Patients requiring MOHs surgery Follow-on Indication: Patients with BCC facial lesions pending MOHs or other surgical procedures	Less toxic therapy than vismodegib for Gorlin Patients to delay MOHs surgeries; low toxicity therapy to delay or minimize surgical intervention for facial BCC tumors	9,000 Gorlin patients needing chronic BCC therapy; 65,000 BCC patients pending surgical treatment for facial tumors that require excision and potential plastic surgery	$900M based upon HedgePath estimates of ~ $4K-$5K monthly cost of therapy for target populations
Lung(2)	Patients with advanced non-squamous cell, non small cell lung cancer (NSCLC) who will be placed on Cisplatin/Pemetrexed IV Therapy	Improve the current median 8-10 month survival achieved with best supportive care	56,000 men and women with late-stage disease on chemotherapy treatment	$1.7 B based on HedgePath estimates of ~ $4K-$5K monthly cost of therapy
Prostate(3)	Patients with non metastatic castrate resistant prostate cancer (NMCRPC) and rising PSA levels on "off-label" androgen deprivation therapy (ADT)	Delay the progression to metastatic disease while preventing or reducing the use of ADT and its associated side-effects	45,000 high-risk men with prostate cancer which may lead to metastases of the bone	$1.5B based on HedgePath estimates of ~ $4K-$5K monthly cost of therapy

References:

(1) *J Am Academy Dermatology, 2006; Skin Cancer Foundation, 2009; International Medicine News, 2011; Seeking Alpha, 2012; BCCNS Support Organization 2014*
(2) *STATS MGU, 2009; Global Industry Analysts, 2010; BMC Health Services, 2011; World Health Organization, 2011; Cost of Treating Lung Cancer, 2012; National Center for Biotechnology Information, 2012*
(3) *J. Urology, 2003; Oncology, 2004; J. Clinical Oncology, 2011; Medscape, 2012; Landes Bioscience, 2012*

Our Business and Financing Strategies

Our goal is to be a leader in the development and commercialization of itraconazole-basedtherapeutics for the treatment of cancer patients. We believe that we can accomplish this goal by:

- rapidly advancing the clinical development of our therapies by leveraging the history of itraconazole's safety and use in humans for anti-fungal indications;
- leveraging our collaboration with Mayne Pharma for product supply during clinical trials, commercial manufacturing and supply following FDA approvals (should regulatory approvals be obtained) and the license of key intellectual property;
- working with key opinion leaders in oncology, including individuals who have studied the efficacy and safety or itraconazole treatments in patients with cancer in Phase II trials;
- implementing clinical programs designed to expedite FDA drug approvals, such as potential breakthrough therapy designation, fast track designation, accelerated approval, and priority review; and
- commercializing and marketing (should regulatory approvals be obtained) with exclusivity via our own intellectual property and licensed intellectual property and knowhow from Mayne Pharma and other potential licensors.

We intend to advance and finance our research and development and commercialization efforts and our working capital needs primarily through:

- securing proceeds from public and private financings and other strategic transactions including through this offering;
- partnering with other pharmaceutical companies, in addition to Mayne Pharma, to assist in the supply, manufacturing and distribution of our product candidate, for which we may receive upfront milestone fees and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing our product candidate to augment such third parties' product profile in the treatment of cancers; and
- potentially seeking government or private foundation grants which would be awarded to us to further develop our anti-cancer therapies.

Risks Associated with Our Business

Our business is subject to many significant risks, as more fully described in the section entitled "Risk Factors" immediately following this prospectus summary. You should read and carefully consider these risks, together with the risks set forth under the section entitled "Risk Factors" and all of the other information in this prospectus, including the financial statements and the related notes included elsewhere in this prospectus, before deciding whether to invest in our common stock. If any of the risks discussed in this prospectus actually occur, our business, financial condition or operating results could be materially and adversely affected. In particular, our risks include, but are not limited to, the following:

- We are a "start-up" company with no history of revenue generating operations, and it will take several years to have any proposed products approved, assuming such approval can be obtained at all. We therefore do not expect to generate revenue for at least the next several years.
- We currently have very limited financial resources and will require substantial additional funding. As of June 30, 2014, we had $271,226 in cash or cash equivalents and a commitment to receive an additional $1,100,000 from Hedgepath, LLC, an affiliated party. If we are unable to raise money in the near term, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts and our business could fail.

- As a result of the pre-revenue nature of our business and our current lack of financial liquidity, our auditors' report for our 2013 financial statements, which is included as part of this prospectus, contains a statement concerning our ability to continue as a "going concern."
- Our limited operating history makes it difficult for you to evaluate our business to date and to assess our future viability.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- We are highly dependent on our collaboration with Mayne Pharma. The loss of our license with Mayne Pharma or Mayne Pharma's inability to supply clinical trial materials for us could lead to the failure of our business.
- Mayne Pharma holds a significant equity stake in our company and has important rights with respect to our company, such as the right to nominate a member(s) of our Board of Directors, the right to invest in future offerings of our securities and the right to require our Chairman and President and Chief Executive Officer to resign if certain corporate milestones are not met;
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We are subject to extensive regulation, and if we fail to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidate, and our ability to generate revenue and the viability of our company will be materially impaired.
- We have licensed or expect to license certain intellectual property from third parties, and such licenses may not continue to be available or may not be available on commercially reasonable terms.

Corporate History

We were founded under the name "Commonwealth Biotechnologies, Inc." in Virginia in 1992, and completed an initial public offering in October 1997 (we refer to our company prior to our emergence from bankruptcy as CBI). CBI previously provided, on a contract basis, specialized life sciences services to the pharmaceutical and biotechnology sector. On January 20, 2011, CBI filed a voluntary petition for bankruptcy. We began our current business in August 2013 as a Delaware corporation following the emergence of CBI from its voluntary bankruptcy proceedings. See "Business-Corporate History."

Principal Offices

We were reincorporated under the laws of the State of Delaware on August 12, 2013 upon consummation of our reincorporation merger. We maintain an address at 324 South Hyde Park Avenue, Suite 350, Tampa, Florida 33606 and our telephone number is (813) 864-2559, and 700 West Harbor Drive, Suite 1104, San Diego, California 92101 where our telephone number is (858) 722-3043.

The Offering

Securities Offered	shares of our common stock.
Offering Price	The assumed public offering price per share of $ is based on the last reported sale price of our common stock on , 2014. However, the final public offering price will be a negotiated price.
Common Stock Outstanding Before the Offering	211,419,937 shares
Common Stock Outstanding After the Offering (assuming the sale of all shares covered hereby)	shares of our common stock
Escrow	Pursuant to an escrow agreement among us, H.C. Wainwright & Co., LLC and American Stock Transfer & Trust Company, as escrow agent, the funds received in payment for the shares sold in this offering will be wired to a non-interest bearing escrow account and held until we and H.C. Wainwright & Co., LLC notify the escrow agent that this offering has closed.
Use of Proceeds	We intend to use the net proceeds from this offering to fund our contract research organization expenses and regulatory consulting programs in support of our anticipated Phase II clinical trials, our joint development efforts with Mayne Pharma, the filing of our Investigational New Drug Application (or IND) with the FDA for SUBA-Itraconazole, and for working capital and general corporate purposes. See "Use of Proceeds."
Risk factors	**Investing in our common stock involves substantial risk.** See the section captioned "Risk Factors" and other information included in this prospectus for a discussion of factors you should consider before deciding to invest in our common stock.
OTCQB Marketplace Symbol	Our common stock is currently quoted on the OTCBB/OTCQB under the symbol "HPPI".

The number of shares outstanding as of the date of this prospectus, as used throughout this prospectus, including in the above discussion and table, unless otherwise indicated, excludes the following, all as of June 30, 2014:

- 20,501,138 shares of our common stock issuable upon the exercise of warrants outstanding with an exercise price of $0.0878;
- 23,541,738 shares of our common stock upon the vesting of restricted stock unit issued in July 2014 and August 2014 pursuant to our 2014 Equity Incentive Plan;
- 9,041,737 shares available for future issuance and grants under our 2014 Equity Incentive Plan; and
- up to shares of common stock issuable upon the exercise of the warrants to be issued to the placement agent in connection with this offering.

Summary Financial Data

The summary financial data below as of and for the years ended December 31, 2013 and 2012 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. The summary financial data below as of June 30, 2014 and 2013 and for the six months ended June 30, 2014 and 2013 have been derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus. The following summary financial information should be read in connection with, and is qualified by reference to, our consolidated financial statements and their related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year ended December 31,		For the Six Months Ended June 30, (unaudited)	
	2013	2012	2014	2013
Revenue	—	—	—	—
Gross margin	—	—	—	—
Operating expenses:				
Research and development	$ 1,065,169	—	$ 1,955,807	—
Chapter 11 expenses	117,324	—	—	$ 117,324
General and administrative	817,316	$ 560,670	346,787	376,800
Total operating expenses	1,999,809	560,670	2,302,594	494,124
Net (loss) income	(1,835,056)	186,366	(2,337,146)	(327,448)
Net (loss) income per share - basic and diluted	(0.10)	0.01	(0.12)	(0.02)
Cash and cash equivalents	217	857,702	271,226	1,112
Total assets	10,217	936,435	300,517	1,474
Total liabilities	776,053	1,069,219	453,871	309,706
Total stockholders' deficit	$ (765,836)	$ (132,784)	$ (153,354)	$ (308,232)
Weighted average shares outstanding basic and diluted	17,940,586	13,646,638	19,760,306	16,976,482

RISK FACTORS

An investment in our common stock involves substantial risks, including the risks described below. You should carefully consider the risks described below before purchasing our common stock. The risks highlighted here are not the only ones that we may face. For example, additional risks presently unknown to us or that we currently consider immaterial or unlikely to occur could also impair our operations. If any of the risks or uncertainties described below or any such additional risks and uncertainties actually occur, our business, prospects, financial condition or results of operations could be negatively affected, and you might lose all or part of your investment.

Risks Related to Our Business

We are a pre-revenue biopharmaceutical company and are thus subject to the risks associated with new businesses in that industry.

We emerged from bankruptcy in August 2013, and the business opportunity we acquired in connection with our reorganization (the development of itraconazole anti-cancer therapies) is a new business opportunity. As such, we are an early stage biopharmaceutical company with no history of revenue-generating operations, and our only assets consist of the intellectual property and related assets contributed to us by our stockholder Hedgepath, LLC on August 13, 2013, in connection with our emergence from bankruptcy. Therefore, we are, and expect for the foreseeable future to be, subject to all the risks and uncertainties inherent in a new business, in particular new businesses engaged in the development of pharmaceuticals. We still must establish and implement many important functions necessary to operate a business, including the clinical development of our product candidate, acquiring additional intellectual property rights related to itraconazole beyond our exclusive Supply and License Agreement with Mayne Pharma for SUBA-Itraconazole*,* establishing our managerial and administrative structure and implementing financial systems and controls.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in their pre-revenue generating stages, particularly those in the pharmaceutical field. Potential investors should carefully consider the risks and uncertainties that a new company with no operating history will face. In particular, potential investors should consider that there is a significant risk that we will not be able to:

- implement or execute our current business plan, or create a business plan that is sound;
- maintain our anticipated management team;
- raise sufficient funds in the capital markets or otherwise to effectuate our business plan;
- determine that the processes and technologies that we have developed are commercially viable; and/or
- attract, enter into or maintain contracts with potential commercial partners such as licensors of technology and suppliers.

If we cannot execute any one of the foregoing, our business may fail, in which case you may lose the entire amount of your investment in our company.

In addition, as a pre-revenue biopharmaceutical company, we expect to encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be able to reach such point of transition or make such a transition, which would have a material adverse effect on our company.

Our limited operating history makes it difficult for you to evaluate our business to date and to assess our future viability.

Currently, our sole line of business is the development and marketing of our itraconazole anti-cancer therapies, and we acquired the assets related to this business opportunity on August 13, 2013 as part of our emergence from bankruptcy. Our pre-bankruptcy historic business operations ceased contemporaneously with our becoming subject to bankruptcy proceedings in 2011, and all assets supporting our earlier lines of business have been disposed of. Accordingly, we only recommenced active operations on August 13, 2013, the date we emerged from bankruptcy.

Moreover, Hedgepath, LLC, from whom we acquired the itraconazole business opportunity as part of our plan of bankruptcy reorganization, was only formed in late 2011 and thus itself has a limited operating history. Our operations are presently limited to planning for clinical trials, arranging for the raising of capital, developing our technology and identifying potential commercial partners. We have not yet demonstrated our ability to complete any clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for product commercialization. Consequently, any predictions you make about our future viability or ability to accomplish our business goals may not be as accurate as they could be if we had a longer operating history.

We are highly dependent on our collaboration with Mayne Pharma, and the loss of this collaboration would materially impair our business plan and viability.

Under our Supply and License Agreement with Mayne Pharma, we have secured exclusive rights to commercialize SUBA-Itraconazole for the treatment of patients with cancer via oral administration in the United States. Mayne Pharma is our sole source supplier of SUBA-Itraconazole, and under such agreement, we must obtain all required supply of SUBA-Itraconazole capsules for our clinical trials and commercialization of the product from Mayne Pharma, except in the limited circumstance where Mayne Pharma has established a secondary supplier and is unable to supply the product. As such, this agreement and our collaboration with Mayne Pharma are critical to our business. In the event that the Mayne Pharma Supply and License Agreement is terminated or Mayne Pharma is unable to supply the product, we will lose the ability to commercialize SUBA-Itraconazole, and our business prospects would be materially damaged. Moreover, if we fail to achieve certain commercialization goals or the funding goals under our agreements with Mayne Pharma, Mayne Pharma has the right to demand the resignation of Nicholas J. Virca, our President and Chief Executive Officer, and Frank E. O'Donnell, Jr., our Executive Chairman, from their positions with our company. In the event that Mr. Virca or Dr. O'Donnell do not submit their resignations in a timely manner, Mayne can terminate the Supply and License Agreement, the loss of which would seriously impair our viability and could lead to the loss of your investment. In addition, Mayne Pharma has the right to terminate the Supply and License Agreement with us if, among other things, we breach any provision of our June 2014 Equity Holders Agreement or Purchase Agreement with Mayne Pharma.

The right of Mayne Pharma to participate in future financings of ours could impair our ability to raise capital.

Pursuant to our Equity Holders Agreement (as described in further detail in the section entitled "Certain Relationships and Related Party Transactions"), Mayne Pharma and its affiliates have been granted a right of first refusal to purchase a pro rata share of any new securities issued by us, which pro rata share would be determined based upon the number of shares of our common stock held by Mayne Pharma and its affiliates on a fully diluted basis as compared to the number of shares of common stock outstanding immediately prior to the offering of the new securities on a fully diluted basis. The existence of such right of participation, or the exercise of such rights, may deter potential investors from providing us needed financing, or may deter investment banks from working with us, which would have a material adverse effect on our ability to finance our company.

The right of Mayne Pharma to introduce accredited investors to us to participate in a private offering of our securities could impair our ability to raise capital.

Under our June 2014 Equity Holders Agreement, Mayne Pharma has been granted the right until June 24, 2016 to introduce accredited investors to us to participate in up to 50% of any private offering of our securities (subject to certain exceptions as described in the Equity Holders Agreement). The existence of such right, or the exercise of such rights, may deter potential private investors from providing us needed financing, or may deter investment banks or other placement agents from working with us, which would have a material adverse effect on our ability to finance our company.

Mayne Pharma may exert significant influence over our business and affairs, and the corporate governance rights afforded to Mayne Pharma under the Equity Holders Agreement may adversely affect the management of our company.

Mayne Pharma currently beneficially owns 44.3% of our outstanding common stock and will beneficially own % of our common stock after completion of this offering, assuming we sell the maximum amount of shares included on the cover of this prospectus. Under the terms of our Equity Holders Agreement, Mayne Pharma has the right to purchase any shares of common stock being transferred or sold by the individual account of our current President and Chief Executive Officer and Executive Chairman. In addition to Mayne Pharma's current common stock ownership, Mayne Pharma also has the right to designate one director to our Board of Directors (and to designate a second director if the size of the Board of Directors is increased to seven directors) until the earlier to occur of: (i) the date that the Supply and License Agreement is terminated or expires, or (ii) the date on which Mayne Pharma along with its affiliates ceases to own ten percent (10%) or more of our issued and outstanding common stock on a fully diluted basis. During this time frame, Mayne Pharma, through its representative on the Board of Directors, holds a veto right in the event that we want to increase or decrease the size of the Board of Directors or replace or remove our President and Chief Executive Officer and Executive Chairman (such veto right being the result of each of the foregoing Board of Director actions requiring the unanimous consent of the Board of Directors). Mayne Pharma's significant ownership of our common stock plus the existence of these additional rights will for the foreseeable future enable Mayne Pharma to exert influence over our company and matters requiring stockholder approval including the election of directors, financing activities or a merger or sale of our assets. Additionally, these rights may limit the ability of our Board of Directors and our management team to make necessary personnel decisions, including adding independent directors to our Board of Directors, which may adversely affect the management of our company, particularly if disputes arise between us and Mayne Pharma (which disputes in and of themselves could have a material adverse effect on our ability to conduct business).

We are dependent upon our officers and directors and their loss could adversely affect our ability to operate.

Our operations are dependent upon a relatively small group of individuals and, in particular, our current officers and directors, including most notably Nicholas J. Virca and Dr. Frank E. O'Donnell, Jr. We believe that our ability to implement our business plans depends on the continued service of these individuals and/or other officers and directors. In particular, Dr. O'Donnell is presently required to commit only 25% of his time to our affairs and, accordingly, he may have conflicts of interest in allocating management time among various business activities, and these conflicts of interest may not be resolved in our favor. We do presently have an executive chairman agreement and an employment agreement with Dr. O'Donnell and Mr. Virca, respectively. However, the agreements are terminable upon 60 days' notice to us with or without good reason. The unexpected loss of the services of one or more of our directors or officers could have a detrimental effect on us.

The requirements of being a public company may strain our resources and divert management's attention.

Prior to Hedgepath, LLC's contribution of certain assets to us in August 2013, the business opportunity and assets we acquired had been operated privately. In addition, although our predecessor, CBI, was a company that filed public reports with the SEC, the business of CBI effectively ceased concurrently with its entry into federal bankruptcy proceedings in 2011. As a consequence, our current business has no historical nexus to that of CBI's.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (which we refer to herein as the Exchange Act), the Sarbanes-Oxley Act, the Dodd-Frank Act and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities (including activities previously undertaken in a private company context) more difficult, time-consuming or costly and increase demand on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our ability to implement our business plans. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from business development activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

Risks Related to Our Financial Position and Need For Additional Capital

We will require substantial additional funding to progress our business. If we are unable to raise additional capital, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts and our business could fail.

We expect that we will be required to incur significant expenses in connection with our ongoing activities, particularly as we engage in efforts to develop and ultimately commercialize our itraconazole anti-cancer therapies.

Accordingly, we will need to obtain long term additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts, and our business might fail.

In addition, our future capital requirements will be significant and will depend on many factors, including:

- the progress and results of our development efforts for SUBA-Itraconazole as a cancer therapy;
- the costs, timing and outcome of clinical trials of our product candidate for one or more types of cancer;
- the costs, timing and outcome of regulatory review of our product candidate for one or more types of cancer;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- competing technological and market developments;
- market acceptance of our product candidate as a treatment for one or more types of cancer;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any product candidate for which we receive marketing approval;
- the revenue, if any, received from commercial sales of any product candidate for which we may receive marketing approval;
- the extent to which we acquire or in-license other products and technologies; and
- legal, accounting, insurance and other professional and business-related costs.

Developing pharmaceutical products, conducting preclinical testing and clinical trials and seeking regulatory approval of such products is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidate, if approved (of which no assurances may be given), may not achieve any level of commercial success. Our commercial revenues, if any, will be derived from sales of a product that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

We may have difficulty in raising capital and may consume resources faster than expected.

We currently do not generate any revenue from product sales or otherwise, and we therefore have a limited source of cash to meet our future capital requirements. We do not expect to generate revenues for the foreseeable future, and we may not be able to raise funds in the future, which would leave us without resources to continue operations and force us to resort to stockholder investments or loans, which may not be available to us. We may have difficulty raising needed capital in the near or longer term as a result of, among other factors, the very early stage of our company, the rights of certain of our stockholders to participate in our future financings and our lack of revenues as well as the inherent business risks associated with our company and present and future market conditions. Also, we may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated. Our inability to raise funds could lead to decreases in the price of our common stock and the failure of our business.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Since we will be unable to generate any revenue from actual sales of products and expect to be in the development stage for the foreseeable future, we will need to seek equity or debt financing to provide the capital required to execute our business plan. We will need significant funding for developing our intellectual property, conducting clinical trials and entering into collaborations with third party partners as well as for working capital requirements and other operating and general corporate purposes.

There can be no assurance that we will be able to raise sufficient capital on acceptable terms, or at all. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be adversely affected to a significant extent.

If we raise additional capital by issuing equity securities, the percentage and/or economic ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock.

Debt financing, if obtained, may involve agreements that include liens on our assets, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, increases in our expenses and requirements that our assets be provided as a security for such debt. Debt financing would also be required to be repaid regardless of our operating results.

If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidate, or to grant licenses on terms that are not favorable to us.

Funding from any source may be unavailable to us on acceptable terms, or at all. If we do not have sufficient capital to fund our operations and expenses, our business could fail.

As a result of our current lack of financial liquidity, our auditors have expressed substantial doubt regarding our ability to continue as a "going concern."

As a result of our current lack of financial liquidity, our auditors' report for our 2013 financial statements, which are included as part of this prospectus, contains a statement concerning our ability to continue as a "going concern." Our lack of sufficient liquidity could make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our public stock price generally.

Our continuation as a "going concern" is dependent upon, among other things, achieving positive cash flow from operations and, if necessary, augmenting such cash flow using external resources to satisfy our cash needs. Our plans to achieve positive cash flow include engaging in offerings of securities, negotiating up-front and milestone payments on pipeline products under development and royalties from sales of our products which secure regulatory approval and any milestone payments associated with such approved products. These cash sources could, potentially, be supplemented by financing or other strategic agreements. However, we may be unable to achieve these goals and therefore may be unable to continue as a going concern.

Risks Related to the Clinical Development of Our Product Candidate

We are very early in our development efforts and have only one product candidate, for which we have not yet conducted any clinical trials in a cancer indication. If we are unable to clinically develop and ultimately commercialize itraconazole as an anti-cancer therapy or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts and have only one product candidate, namely SUBA-Itraconazole for the treatment of cancer. While itraconazole has previously been approved by the FDA for use as an anti-fungal agent, the use of itraconazole to treat cancer has not been approved and has been subject to limited clinical testing by others. Moreover, we have not engaged in any such testing ourselves, and our operations as of our emergence from bankruptcy in August 2013 have been limited to developing our own intellectual property and know how, while acquiring the technology and rights of others in order to pursue the clinical development of the itraconazole formulation, SUBA-Itraconazole, as a cancer therapy.

Therefore, our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on our ability to develop and eventually commercialize our product candidate. The positive development of our product candidate will depend on several factors, including the following:

- timely commencement and completion of clinical trials;
- successful preparation of regulatory filings and receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and potential regulatory exclusivity for our product candidate and protecting our rights in our intellectual property portfolio;
- maintaining our agreement with Mayne Pharma to produce product needed for clinical testing and, potentially if approvals are obtained, for commercial sale;
- launching commercial sales of our product, if and when approved for one or more indications, whether alone or in collaboration with others;
- acceptance of the product for one or more indications, if and when approved, by patients, the medical community and third party payors;
- protection from generic substitution based upon our own or licensed intellectual property rights;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of our product following approval, if any.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to clinically develop and commercialize SUBA-Itraconazole as a cancer therapy, which would materially harm our business.

In addition, given our current limited financial resources, we are currently focusing our efforts on one key cancer indication, namely basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome, also known as Gorlin Syndrome. We are thus faced with the risk that SUBA-Itraconazole could be ineffective in addressing this particular initial cancer indication, and if our efforts to demonstrate the efficacy of SUBA-Itraconazole in treating basal cell carcinoma in this target patient population are not positive, we may lack the resources to expand our efforts into other cancer indications.

If we are unable to convince physicians as to the benefits of SUBA-Itraconazole as a cancer therapy, if and when it is approved, we may incur delays or additional expense in our attempt to establish market acceptance.

Use of SUBA-Itraconazole as a cancer therapy will require physicians to be informed regarding the intended benefits of the product for a new indication. The time and cost of such an educational process may be substantial. Inability to carry out this physician education process may adversely affect market acceptance of SUBA-Itraconazole as a cancer therapy. We may be unable to timely educate physicians in sufficient numbers regarding our intended application of SUBA-Itraconazole to achieve our marketing plans or to achieve product acceptance. Any delay in physician education or acceptance may materially delay or reduce demand for our product candidate. In addition, we may expend significant funds toward physician education before any acceptance or demand for SUBA-Itraconazole as a cancer therapy is created, if at all.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidate.

The risk of failure for product candidates in clinical development is high. It is impossible to predict when our sole product candidate, SUBA-Itraconazole for the treatment of cancer, will prove effective and safe in humans or will receive regulatory approval for any form of cancer or any other indication. Before obtaining marketing approval from regulatory authorities for the sale of SUBA-Itraconazole as a cancer therapy, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidate in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Moreover, the outcome of early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidate, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidate may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs, which would be time consuming and costly;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials may be greater than we anticipate;
- the supply or quality of materials necessary to conduct clinical trials of our product candidate may be insufficient or inadequate;
- our product candidate may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials; and
- interactions with other drugs.

If we are required to conduct additional clinical trials or other testing of our product candidate beyond those that we currently contemplate, if we are unable to complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidate for one or more indications;
- not obtain marketing approval at all for one or more indications;
- obtain approval for indications or patient populations that are not as broad as intended or desired (particularly, in our case, for different types of cancer);
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidate or allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidate and may harm our business and results of operations.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidate if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidate, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the patient referral practices of physicians
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidate, which would cause the value of our company to decline and otherwise materially and adversely affect our company.

If serious adverse or unacceptable side effects are identified during the development of our product candidate, we may need to abandon or limit such development, which would adversely affect our company.

If clinical testing of SUBA-Itraconazole for the treatment of cancer results in undesirable side effects or demonstrates characteristics that are unexpected, we may need to abandon such development or limit such development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. If we are unable to develop SUBA-Itraconazole for the treatment of cancer due to reported adverse effects or characteristics, our business would be severely harmed.

For the foreseeable future, we expect to expend our limited resources to pursue a particular product candidate, leaving us unable to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of clinical and commercial development.

Because we have limited financial and managerial resources, we will focus for the foreseeable future only on the clinical development of SUBA-Itraconazole for the treatment of cancer as a therapy for basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome, also known as Gorlin Syndrome. As a result, we may forego or be unable to pursue opportunities with other product candidates or for indications other than those we intend to pursue that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs related to SUBA-Itraconazole for the treatment of cancer may not yield any commercially viable therapies. Because of this concentration of our efforts, our business will be particularly subject to significant risk of failure of our one current product candidate.

We expect to rely on collaborations with third parties for key aspects of our business. If we are unable to secure or maintain any of these collaborations, or if these collaborations do not achieve their goals, including most notably our collaboration with Mayne Pharma, our business would be adversely affected.

We presently have very limited capabilities for drug development and do not yet have any capability for manufacturing, sales, marketing or distribution. Accordingly, we expect to enter into collaborations with other companies that we believe can provide such capabilities. These collaborations may also provide us with important funding for our development programs. One such collaboration was entered into in September 2013 with Mayne Pharma for SUBA-Itraconazole under an exclusive Supply and License Agreement.

There is a risk that we may not be able to maintain our current collaboration or to enter into additional collaborations on acceptable terms or at all, which would leave us unable to progress our business plan. We will face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator’s evaluation of a number of factors. If we are unable to maintain or reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of our product candidate, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

Moreover, even if we are able to maintain and/or enter into such collaborations, such collaborations may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of our product candidate, might lead to additional responsibilities for us with respect to such product candidate, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators could independently develop or be associated with products that compete directly or indirectly with our product candidate;
- collaborators could have significant discretion in determining the efforts and resources that they will apply to our arrangements with them;
- should our product candidate achieve regulatory approval, a collaborator with marketing and distribution rights to our product candidate may not commit sufficient resources to the marketing and distribution of such product;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability, and we do not have the right to sue infringers of the rights granted to us by Mayne Pharma under the Supply and License Agreement; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to either find alternative collaborators (which we may be unable to do) or raise additional capital to pursue further development or commercialization of our product candidate on our own.

Our business would be materially or perhaps significantly harmed if any of the foregoing or similar risks comes to pass with respect to our key collaborations

We have contracted with Mayne Pharma and may contract with other third parties, for the manufacture of our product candidates for clinical testing and expect to continue to do so for commercialization. This reliance on third parties, and in particular Mayne Pharma, increases the risk that we will not have sufficient quantities of our product candidate(s) or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing capabilities. We expect to rely on Mayne Pharma for the manufacture of our product candidate, SUBA-Itraconazole, for clinical testing, as well as for commercial manufacture if our product candidate ultimately receives marketing approval. This reliance on Mayne Pharma leaves us exposed to the risk that we will not have sufficient quantities of our product candidate or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. In addition, the possibility of a business interruption event with Mayne Pharma or any other manufacturer may occur, such as bankruptcy, factory contamination or natural disaster, which may result in the inability to obtain product, which would cause our business prospects to be adversely impacted.

Moreover, we may be unable to maintain our agreement with Mayne Pharma or establish any agreements with other third party manufacturers or to do so on acceptable terms should we have the ability and the need to do so. Even though we have established an agreement with Mayne Pharma or if we are able to establish agreements with other third party manufacturers, reliance on third party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidate or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidate or products.

In addition, our product candidate and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Also, any performance failure on the part of Mayne Pharma could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If Mayne Pharma cannot perform as agreed, we may not be able to continue developing SUBA-Itraconazole.

Risks Related to the Commercialization of Our Product Candidate

Even if SUBA-Itraconazole for the treatment of cancer receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success.

Even if SUBA-Itraconazole for the treatment of cancer receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third party payors and others in the medical community. For example, current cancer treatments such as chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments. If our product candidate does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of SUBA-Itraconazole for the treatment of cancer, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

If we are unable to establish sales, marketing and distribution capabilities, we may not be able to commercialize our product candidate if and when it is approved.

We do not have a sales or marketing infrastructure. To achieve any level of commercial success for any product for which we have obtained marketing approval, we will need to establish a sales and marketing organization or outsource sales and marketing functions to third parties.

There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If approved, factors that may inhibit our efforts to commercialize our product on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our product;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may be unable to enter into arrangements with third parties to sell, market and distribute our product candidate or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product effectively. If we do not establish sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be able to commercialize our product candidate, which would have a material adverse effect on our company.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidate, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of cancer. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs, and we may be unable to effectively compete with these companies for these or other reasons.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals.

Our ability to commercialize any product candidate also will depend in part on the extent to which coverage and adequate reimbursement for our product candidate will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to commercialize any product candidate for which we obtain marketing approval.

In addition, there may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors. Third party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidate in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot defend ourselves against claims that our product candidate or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- damage to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently do not have product liability insurance coverage, which leaves us exposed to any product-related liabilities that we may incur. We may be unable to obtain insurance on reasonable terms or at all. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products (particularly itraconazole, and the formulation of SUBA-Itraconazole in particular, as an anti-cancer therapy), or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to commercialize our technology and products may be impaired.

Our business plan depends in large part on our ability to obtain and maintain patent protection in the United States with respect to our proprietary technology and products, and in particular, the rights to develop SUBA-Itraconazole as an anti-cancer therapy. We seek to protect our proprietary position through our exclusive license for SUBA-Itraconazole with Mayne Pharma, and by filing patent applications in the United States related to our novel technologies and product candidate and also expect to license additional applicable patents from third parties.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances (particularly in collaboration scenarios such as our agreement with Mayne Pharma), we may not have the right to control (in whole or in part) the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Patent reform legislation could further increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. Accordingly, since we have patent applications pending and plan to file for additional patents in the future, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of our product candidate, patents protecting such candidate might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Neither we nor Mayne Pharma has conducted a comprehensive freedom to operate search in the United States relating to the use of itraconazole in the treatment of cancer, and as a result, patents may in the future be issued, or may already have issued, to third parties that would prevent us from developing SUBA-Itraconazole for our intended cancer indications. If such patents have issued or are issued in the future, and such patents are determined to be valid, we or Mayne Pharma could be required to obtain a license to such patents in order to allow us to continue the development of SUBA-Itraconazole for our intended indications. We or Mayne Pharma may be unable to obtain such licenses on reasonable terms or at all.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our owned or licensed patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Furthermore, we do not have the right to sue infringers of the rights granted to us by Mayne Pharma under the Supply and License Agreement, so we will be reliant upon them to take any action necessary to protect these patents. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly.

We have licensed or expect to license certain intellectual property from third parties, and such licenses may not continue to be available or may not be available on commercially reasonable terms.

We have and/or expect to enter into licenses with third parties that hold intellectual property, including patent rights, that are important or necessary to the development of itraconazole, and SUBA-Itraconazole in particular, as an anti-cancer therapy, and it may be necessary for us to use the patented or proprietary technology of third parties, such as Mayne Pharma, to commercialize itraconazole as an anti-cancer therapy, in which case we have or would be required to obtain a license from these third parties on commercially reasonable terms, or else our business could be harmed, possibly materially. If we were not able to maintain or obtain such licenses, or were not able to maintain or obtain such licenses on commercially reasonable terms, our business could be harmed, possibly substantially.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on our business.

Our business will depend upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our primary product candidate or other products and technology, including interference or derivation proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. Further, we are obliged under the Supply and License Agreement with Mayne Pharma to indemnify it with respect to any claims, losses, damages or expenses arising from the research, development, or commercialization of SUBA-Itraconazole and any actual or alleged infringement of third party intellectual property rights. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose rights that are important to our business.

We are and expect to be party to one or more license or similar agreements that may impose due diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under current or future licenses, our counterparties may have the right to terminate these agreements, in which case we might not be able to develop, manufacture or market any product that is covered by these agreements (particularly SUBA-Itraconazole as an anti-cancer therapy) or may face other penalties under the agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal and Compliance Matters

If we fail to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidate, and our ability to generate revenue and the viability of our company will be materially impaired.

Our product candidate (SUBA-Itraconazole as an anti-cancer therapy) and the activities associated with its clinical development and commercialization, including matters relating to design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA (including under the Federal Food, Drug and Cosmetic Act) and other regulatory agencies in the United States. Failure to obtain marketing approval for our product candidate will prevent us from commercializing the product candidate. We have not received approval to market SUBA-Itraconazole as an anti-cancer therapy or any other product from regulatory authorities in any jurisdiction and it will likely be years before we are even eligible to receive such approval.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate’s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or prevent or limit commercial use of our product. In particular, new cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. Even if our product candidate receives marketing approval for one or more indications, of which no assurances may be given, the accompanying labels may limit the approved use of our drug, which could limit sales of the product.

The process of obtaining marketing approvals in the United States is very expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies.

In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of our product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidate, the commercial prospects for our product candidate will be harmed and our ability to generate revenues, and the viability of our company generally, will be materially impaired.

We may also be subject to healthcare laws, regulation and enforcement; our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

Although we currently do not directly market or promote any products, we may also be subject to several healthcare regulations and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Health Insurance Portability and Accountability Act of 1996 (or HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

We will likely seek approval of SUBA-Itraconazole as an anti-cancer therapy under an expedited procedure, which may not be available to us.

It is our intention to seek to avail ourselves of the FDA's 505(b)(2) approval procedure where it is appropriate to do so, particularly for SUBA-Itraconazole as an anti-cancer therapy since itraconazole has previously been approved for another indication. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act permits an applicant to file a New Drug Application (or NDA) with the FDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and the FDA's findings of safety and effectiveness based on certain preclinical testing or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product.

If this approval pathway is not available to us with respect to our product candidate, the time and cost associated with developing and commercializing such candidate may be prohibitive and our business strategy could be materially and adversely affected.

A fast track designation by the FDA, if we obtain such a designation, may not actually lead to a faster development or regulatory review or approval process.

We may seek “fast track” designation for our product candidate for one or more indications. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe that SUBA-Itraconazole as an anti-cancer therapy may be eligible for this designation, we cannot assure you that the FDA would decide to grant it should we apply for this designation. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

A breakthrough therapy designation by the FDA for our product candidate, if we obtain such a designation, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidate will receive marketing approval.

We may seek a “breakthrough therapy” designation for our product candidate. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that SUBA-Itraconazole as an anti-cancer therapy meets the criteria for designation as a breakthrough therapy for one or more indications, the FDA may disagree and instead determine not to make such designation. Even if such designation is granted, of which no assurances may be given, the receipt of a breakthrough therapy designation for our product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if SUBA-Itraconazole as an anti-cancer therapy qualifies as a breakthrough therapy for one or more indications, the FDA may later decide that it no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened, which would deny us the benefits of such designation.

We may seek but be unable to obtain orphan drug exclusivity for our product candidate. If our competitors are able to obtain orphan drug exclusivity for their products that are the same drug as our product candidate, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities may designate drugs for relatively small patient populations as orphan drugs. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of market exclusivity, which, subject to certain exceptions, precludes the FDA from approving another marketing application for the same drug for the same indication for that time period. The applicable market exclusivity period is seven years in the United States.

Obtaining orphan drug exclusivity for SUBA-Itraconazole as an anti-cancer therapy may be important to our commercial strategy. If a competitor obtains orphan drug exclusivity for and approval of a product with the same indication as our itraconazole product before we do, and if the competitor’s product is the same drug or a similar medicinal product as ours, we could be excluded from the market. Even if we obtain orphan drug exclusivity for SUBA-Itraconazole as an anti-cancer therapy, we may not be able to maintain it. For example, if a competitive product that is the same drug or a similar medicinal product as our product candidate is shown to be clinically superior to our product candidate, any orphan drug exclusivity we have obtained will not block the approval of such competitive product. In addition, orphan drug exclusivity will not prevent the approval of a product that is the same drug as our product candidate if the FDA finds that we cannot assure the availability of sufficient quantities of the drug to meet the needs of the persons with the disease or condition for which the drug was designated. If one or more of these events occur, it could have a material adverse effect on our company.

Even if we obtain marketing approval for our product candidate, we could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems.

Even if we obtain marketing approval for SUBA-Itraconazole as an anti-cancer therapy, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, we will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. In addition, even if marketing approval of our product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a risk evaluation and mitigation strategy. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If our product candidate receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we or any third party partners of ours do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our product, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such product, our manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of the product;
- restrictions of product distribution use;
- requirements to conduct post-marketing studies or clinical trials;
- the need to utilize warning letters;
- suspension or withdrawal of marketing approvals;
- withdrawal of the product from the market or product recalls;
- refusal by regulatory authorities to approve pending applications or supplements to approved applications that we submit;
- fines, restitution or disgorgement of profits or revenues;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

We may face similar issues in connection with non-compliance with non-U.S. regulatory requirements.

Risks Related to this Offering

Our management will have broad discretion in how we use the net proceeds of this offering.

Our management will have considerable discretion over the use of proceeds from this offering. You will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used in a manner which you may consider most appropriate. Furthermore, you will have no direct say on how our management allocates the net proceeds of this offering. Until the net proceeds are used, they may be placed in investments that do not produce significant income or that may lose value.

You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future

You will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of a shares of common stock offered in this offering at the public offering price of $ per share, and after deducting placement agent commissions and estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of $ per share, or %, at the public offering price. In addition, in the past, we issued warrants to acquire shares of common stock. To the extent that these warrants, or options we will grant to our officers, directors and employees, are ultimately exercised, you will sustain future dilution. We may also acquire or license other technologies or finance strategic alliances by issuing equity, which may result in additional dilution to our stockholders.

In making your investment decision, you should understand that we and the placement agent have not authorized any other party to provide you with information concerning us or this offering.

You should carefully evaluate all of the information in this prospectus before investing in our company. We may receive media coverage regarding our company, including coverage that is not directly attributable to statements made by our officers, that incorrectly reports on statements made by our officers or employees, or that is misleading as a result of omitting information provided by us, our officers or employees. We and the placement agent have not authorized any other party to provide you with information concerning us or this offering, and you should not rely on this information in making an investment decision.

Risks Related to Our Common Stock Generally

An active trading market for our common stock may not develop or be sustained.

As we only emerged from bankruptcy in August 2013 and are in the early stages of our business plan, an investment in our company will likely require a long-term commitment, with no certainty of return. Although our common stock is listed for quotation on the Over-The-Counter Bulletin Board (or OTCBB) and the OTCQB marketplace operated by OTC Markets Group, Inc., trading has been very limited and we cannot predict whether an active market for our common stock will ever develop in the future. In the absence of an active trading market:

- investors may have difficulty buying and selling or obtaining market quotations;
- market visibility for shares of our common stock may be limited; and
- a lack of visibility for shares of our common stock may have a depressive effect on the market price for shares of our common stock.

The OTCBB and OTCQB markets are relatively unorganized, inter-dealer, over-the-counter markets that provide significantly less liquidity than NASDAQ or the NYSE MKT (formerly known as the NYSE AMEX market). This illiquid trading market for our common stock may make it difficult for you to dispose of your common stock at desirable prices or at all. Moreover, there is a risk that our common stock could be delisted from the OTCBB and OTCQB, in which case it might be listed on the so called “Pink Sheets”, which is even more illiquid than the OTCQB.

The lack of an active market impairs your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

We may not maintain qualification for OTC Bulletin Board or OTCQB inclusion, and therefore you may be unable to sell your shares.

Our common stock is eligible for quotation on the OTCBB and OTCQB. However, trading of our common stock could be suspended. If for any reason our common stock does not become eligible or maintain eligibility for quotation on the OTCBB or OTCQB or a public trading market does not develop, purchasers of shares of our common stock may have difficulty selling their shares should they desire to do so. If we are unable to satisfy the requirements for quotation on the OTCBB and OTCQB, any quotation in our common stock could be conducted in the "pink sheets" market. As a result, a purchaser of our common stock may find it more difficult to dispose of, or to obtain accurate quotations as to the price of their shares. This would materially and adversely affect the liquidity of our securities.

Even if a market for our common stock develops, the market price of our common stock may be significantly volatile, which could result in substantial losses for purchasers.

The market price for our common stock may be significantly volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial or operational estimates or projections;
- conditions in markets generally;
- changes in the economic performance or market valuations of companies similar to ours; and
- general economic or political conditions in the United States or elsewhere;

In particular, the market prices for securities of biotechnology companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- changes in our relationship with Mayne Pharma, including if Mayne Pharma elects to exercise their right to remove our Chief Executive and President and Executive Chairman if certain corporate milestones are not met;
- any delay in or the results of our clinical trials;
- the announcements of clinical trial data, and the investment community's perception of and reaction to those data;
- the results of clinical trials conducted by others on products that would compete with our product candidate;
- any delay or failure to receive approval from the FDA and other regulatory agencies or bodies;
- our inability to commercially launch our product or market and generate sales of our product;
- failure of our product, even if approved for marketing, to achieve any level of commercial success;
- our failure to obtain or maintain patent protection for any of our technologies and product or the issuance of third party patents that cover our technologies or product;
- developments or disputes concerning our product's intellectual property rights;
- our competitors' technological innovations;
- general and industry-specific economic conditions that may affect our expenditures;
- changes in market valuations of similar companies;

- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents;
- failure to adequately manufacture our product through third parties for purposes of clinical trials or actual sales;
- future sales of our common stock or other securities;
- period-to-period fluctuations in our financial results; and
- low trading volume of our common stock.

In addition, if we fail to reach an important research, development or commercialization milestone or result by a publicly expected deadline, even if by only a small margin, there could be significant impact on the market price of our common stock. Additionally, as we approach the announcement of anticipated significant information and as we announce such information, we expect the price of our common stock to be particularly volatile, and negative results would have a substantial negative impact on the price of our common stock.

In some cases, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our business operations and reputation.

Our management and two significant stockholders collectively own a substantial majority of our common stock and voting power.

Collectively, our officers, our directors and two significant stockholders (HPLLC and Mayne Pharma) own or exercise voting and investment control of approximately 91.1% of our outstanding common stock. As a result, investors may be prevented from affecting matters involving our company, including:

- the composition of our Board of Directors and, through it, any determination with respect to our business direction and policies, including the appointment and removal of officers;
- any determinations with respect to mergers or other business combinations;
- our acquisition or disposition of assets; and
- our corporate financing activities.

Furthermore, this concentration of voting power could have the effect of delaying, deterring or preventing a change of control or other business combination that might otherwise be beneficial to our stockholders. This significant concentration of share ownership may also adversely affect the trading price for our common stock because investors may perceive disadvantages in owning stock in a company that is controlled by a small number of stockholders.

Future sales of our common stock in the public market could lower the price of our common stock and impair our ability to raise funds in future securities offerings.

Significant blocks of our stock are held by HPLLC and Mayne Pharma, and these entities also hold warrants to purchase our common stock. Future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then prevailing market price of our common stock and could make it more difficult for us to raise funds in the future through a public offering of our securities.

Our common stock may be considered a "penny stock," and thereby be subject to additional sale and trading regulations that may make it more difficult to sell.

Our common stock may be considered to be a "penny stock" if it does not qualify for one of the exemptions from the definition of "penny stock" under Section 3a51-1 of the Securities Exchange Act of 1934, as amended (or the Exchange Act). Our common stock may be a "penny stock" if it meets one or more of the following conditions: (i) the stock trades at a price less than $5 per share; (ii) it is not traded on a “recognized” national exchange; or (iii) is issued by a company (such as ours) that has been in business less than three years with net tangible assets less than $5 million.

The principal result or effect of being designated a “penny stock” is that securities broker-dealers participating in sales of our common stock will be subject to the “penny stock” regulations set forth in Rules 15g-2 through 15g-9 promulgated under the Exchange Act. For example, Rule 15g-2 requires broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document at least two business days before effecting any transaction in a penny stock for the investor’s account. Moreover, Rule 15g-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to: (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor’s financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult and time consuming for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

FINRA sales practice requirements may also limit your ability to buy and sell our common stock, which could depress the price of our shares.

FINRA rules require broker-dealers to have reasonable grounds for believing that an investment is suitable for a customer before recommending that investment to the customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer’s financial status, tax status and investment objectives, among other things. Under interpretations of these rules, FINRA believes that there is a high probability such speculative low-priced securities will not be suitable for at least some customers. Thus, FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our shares, have an adverse effect on the market for our shares, and thereby depress our share price.

You may face significant restrictions on the resale of your shares due to state “blue sky” laws.

Each state has its own securities laws, often called “blue sky” laws, which (1) limit sales of securities to a state’s residents unless the securities are registered in that state or qualify for an exemption from registration, and (2) govern the reporting requirements for broker-dealers doing business directly or indirectly in the state. Before a security is sold in a state, there must be a registration in place to cover the transaction, or it must be exempt from registration. The applicable broker-dealer must also be registered in that state.

We do not know whether our securities will be registered or exempt from registration under the laws of any state. A determination regarding registration will be made by those broker-dealers, if any, who agree to serve as market makers for our common stock. We have not yet applied to have our securities registered in any state and will not do so until we receive expressions of interest from investors resident in specific states after they have viewed this prospectus. There may be significant state blue sky law restrictions on the ability of investors to sell, and on purchasers to buy, our securities. You should therefore consider the resale market for our common stock to be limited, as you may be unable to resell your shares without the significant expense of state registration or qualification.

There may be limitations on the effectiveness of our internal controls, and a failure of our control systems to prevent error or fraud may materially harm our company.

Proper systems of internal controls over financial accounting and disclosure are critical to the operation of a public company. As we are a start-up company, we are at the very early stages of establishing, and we may be unable to effectively establish such systems. This would leave us without the ability to reliably assimilate and compile financial information about our company and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on our company from many perspectives.

Moreover, we do not expect that disclosure controls or internal control over financial reporting, even if established, will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to prevent error or fraud could materially and adversely impact us.

We may be unable to complete our analysis of our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting for our fiscal year ended December 31, 2014. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting, as well as a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting.

We are in the early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

If we are unable to assert that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC.

Because we became public by means other than a traditional initial public offering, we may not be able to attract the attention of major brokerage firms.

Our business was created when our certain operating assets were contributed to our company in August 2013 as our company was a "shell company" emerging from bankruptcy. Since our current business became a public company by means other than a traditional initial public offering, investors and securities analysts may be reluctant to invest in our provide research coverage of us. This stigma could impair our fundraising opportunities and our reputation generally.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Anti-takeover provisions in our charter documents and Delaware law could discourage, delay or prevent a change in control of our company and may affect the trading price of our common stock.

We are a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders.

In addition, our certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. In particular, our certificate of incorporation and amended and restated bylaws, among other matters:

- permit our Board of Directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that all vacancies on our Board of Directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election;
- provide that special meetings of stockholders may only be called by our Chairman, Chief Executive Officer, President, or any other executive officers, our board of directors or a super-majority (66 2/3%) of our stockholders; and
- provide that only a super-majority of our stockholders (66 2/3%) may amend our amended and restated bylaws.

The financial and operational projections that we may make from time to time are subject to inherent risks.

The projections that our management may provide from time to time (including, but not limited to, those relating to potential peak sales amounts, product approval, production and supply dates, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in this prospectus should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

We do not intend to pay dividends on our common stock.

We have never declared or paid any cash dividend on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends for the foreseeable future. Therefore, you should not invest in our common stock in the expectation that you will receive dividends.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains a number of “forward-looking statements”. Specifically, all statements other than statements of historical facts included in this prospectus regarding our financial position, business strategy and plans and objectives of management for future operations are forward-looking statements. These forward-looking statements are based on the beliefs of management at the time these statements were made, as well as assumptions made by and information currently available to management. When used in this prospectus and the documents incorporated by reference herein, the words “anticipate,” “believe,” “estimate,” “expect,” “may,” “will,” “continue” and “intend,” and words or phrases of similar import, as they relate to our financial position, business strategy and plans, or objectives of management, are intended to identify forward-looking statements. These statements reflect our current view with respect to future events and are subject to risks, uncertainties and assumptions related to various factors.

You should understand that the following important factors, in addition to those discussed in our periodic reports to be filed with the SEC under the Exchange Act, could affect our future results and could cause those results to differ materially from those expressed in such forward-looking statements:

A variety of factors, some of which are outside our control, may cause our operating results to fluctuate significantly. They include:

- our lack of operating history;
- our current lack of the capital resources needed to progress our business plan;
- acceptance of our business model (namely the repurposing of the drug itraconazole (currently approved as an anti-fungal agent) for the treatment of cancer) by investors and potential commercial collaborators;
- our current and future capital requirements and our ability to satisfy our capital needs;
- our ability to complete required clinical trials of our product candidate and obtain approval from the FDA or other regulatory agencies in different jurisdictions;
- our ability to secure and maintain key development and commercialization partners for our product candidate;
- our ability to obtain, maintain or protect the validity of our patents and other intellectual property;
- our ability to internally develop new inventions and intellectual property;
- our ability to retain key executive members; and
- interpretations of current laws and the passages of future laws, rules and regulations applicable to our business.

Although we believe that our expectations (including those on which our forward-looking statements are based) are reasonable, we cannot assure you that those expectations will prove to be correct. Should any one or more of these risks or uncertainties materialize, or should any underlying assumptions prove incorrect, actual results may vary materially from those described in our forward-looking statements as anticipated, believed, estimated, expected or intended.

Except for our ongoing obligations to disclose material information under the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or any other reason. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this prospectus and the documents incorporated by reference herein might not occur.

USE OF PROCEEDS

We anticipate that we will receive net proceeds of approximately $ from this offering (after deducting the Placement Agent's selling commissions and offering-related expenses). We currently expect to use the net proceeds from this offering as follows:

- funding our contract research organization expenses and regulatory consulting programs in support of our anticipated Phase II/III clinical trials;
- funding our joint development efforts with Mayne Pharma;
- costs associated with the filing of our INDs for SUBA-Itraconazole; and
- for working capital and general corporate purposes (including the repayment of approximately $42,000 to former officers and employees of CBI which is due by December 31, 2014).

Notwithstanding the foregoing, our management will have broad discretion on the allocation of the proceeds from this offering. The above approximation of our net proceeds represents an estimate only of the use of the net proceeds of this offering based upon our plans and current economic and industry conditions, and is subject to reallocation. The expenses to be incurred in developing and pursuing our business plan cannot be predicted with any degree of certainty. Specific allocation of proceeds will depend ultimately on, among other things, the progress and timing of our product development, marketing efforts and the timing and results of any required future debt and/or equity financings.

We believe, based on current estimates, that if we sell the full offering amount, we will be able to fund our operations until approximately . We cannot assure you that our cost estimates will prove to be accurate or that unforeseen events, problems or delays will not occur that would require us to seek additional debt and/or equity funding, which may not be available on favorable terms, sooner than expected to meet our working capital requirements.

DIVIDEND POLICY

We have never declared or paid any cash dividend on our capital stock. We do not anticipate paying any cash dividends in the foreseeable future and we intend to retain all of our earnings, if any, to finance our growth and operations and to fund the expansion of our business. Payment of any dividends will be made in the discretion of our Board of Directors, after its taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion. Any dividends that may be declared or paid on our common stock, must also be paid in the same consideration or manner, as the case may be, on our shares of preferred stock, if any.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Holders of Common Stock

As of the date of this prospectus, we have approximately 50 holders of record of our common stock. The number of record holders does not include persons, if any, who hold our common stock in nominee or "street name" accounts through brokers.

Market for Common Stock

Our common stock is quoted on the OTCBB and OTCQB markets under the symbol "HPPI." The following table sets forth, for the periods indicated, the high and low sales prices per share of our common stock as reported by the OTC Market Group:

Period Ended	High	Low
March 31, 2014	$0.30	$0.08
June 30, 2014	$0.23	$0.05
March 31, 2013	$0.10	$0.01
June 30, 2013	$0.12	$0.03
September 30, 2013	$0.23	$0.05
December 31, 2013	$0.18	$0.08
March 31, 2012	$0.05	$0.01
June 30, 2012	$0.03	$0.02
September 30, 2012	$0.02	$0.02
December 31, 2012	$0.02	$0.01

These sales prices were obtained from the OTC Market Group, Inc. and do not necessarily reflect actual transactions, retail markups, mark downs or commissions. As of September [ ], 2014, the last reported sales price of a share of our common stock on the OTCBB and OTCQB was $[ ]. No assurance can be given that an established public market will develop in our common stock, or if any such market does develop, that it will continue or be sustained for any period of time.

Transfer Agent

Our stock transfer agent is Computershare, Inc, which is located at 350 Indiana St. Suite 750, Golden, Colorado 80401, Telephone:(303) 262-0678.

Securities Authorized for Issuance under Equity Compensation Plans

The following table indicates as of the date of this prospectus the shares of common stock authorized for issuance under our 2014 Equity Incentive Plan, subject to approval by our majority stockholders:

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance (c)
Equity compensation plans approved by security holders(1)	23,541,738	n/a	9,041,737
Equity compensation plans not approved by security holders	—	n/a	—

(1) Consists solely of restricted stock units which vest on the earlier to occur of September 3, 2016 and the receipt of written notice of acceptance for the filing of an NDA by us for SUBA-Itraconazole by the relevant regulatory authority.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2014:

- on an actual basis;
- on a pro forma basis to give effect to the conversion of 500,000 shares of Series A preferred stock into 170,000,739 shares of common stock on August 14, 2014; and
- on a pro forma basis to give effect to our issuance and sale of shares of our common stock in this offering at an assumed public offering price of $ per share (which is the closing price of the common stock on , 2014), after deducting estimated placement agent fees and estimated offering expenses payable by us.

	As of June 30, 2014		
	Actual	Pro Forma adjusted for conversion of preferred	Pro Forma
Cash and cash equivalents	$ 217,226	$ 217,226	$
Stockholders' (deficit) equity:			
HPLLC Note	(1,100,000)	(1,100,000)	
Common stock, $0.0001 par value, 340,000,000 shares authorized and 41,419,198 shares issued and outstanding at June 30, 2014, actual; 340,000,000 shares authorized and 211,419,937 shares issued and outstanding at June 30, 2014, pro forma adjusted	4,142	21,142	
Series A Preferred stock, $0.0001 par value; 500,000 shares authorized and 500,000 shares issued and outstanding at June 30, 2014, actual; 500,000 shares authorized and no shares issued and outstanding at June 30, 2014, pro forma adjusted	50	—	
Additional paid-in capital	31,527,255	31,510,305	
Accumulated deficit	(30,584,801)	(30,584,801)	
Total stockholders' equity (deficit)	(153,354)	(153,354)	
Total capitalization	$ 63,872	$ 63,872	

The number of shares outstanding as of the date of this prospectus, as used throughout this prospectus, including in the above discussion and table, unless otherwise indicated, excludes the following, all as of June 30, 2014:

- 20,501,138 shares of our common stock issuable upon the exercise of warrants outstanding with an exercise price of $0.0878;
- 23,541,738 shares of our common stock to be issued upon the vesting of restricted stock units issued in July 2014 and August 2014 pursuant to our 2014 Equity Incentive Plan;
- 9,041,737 shares available for future issuance and grants under our 2014 Equity Incentive Plan; and
- up to shares of common stock issuable upon the exercise of the warrants to be issued to the placement agent in connection with this offering.

DILUTION

If you purchase shares in this offering your interest will be diluted immediately to the extent of the difference between the assumed public offering price of $ per share (which is the closing price of the common stock on , 2014) and the as adjusted net tangible book value per share of our common stock immediately following this offering.

Our pro forma net tangible book value as of June 30, 2014 was approximately $946,646, or approximately $0.02 per share. Pro forma net tangible book value per share represents our total tangible assets less total tangible liabilities, divided by the number of shares of common stock outstanding as of June 30 2014 (on a pro forma basis taking into account the conversion of our Series A preferred stock into 170,000,739 shares of common stock, which occurred on August 14, 2014). Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers in this offering and the adjusted net tangible book value per share of common stock immediately after completion of this offering.

Assuming the sale of shares of common stock in this offering at a public offering price of $ per share, and after deducting the placement agent's commission and estimated offering expenses, our adjusted net tangible book value as of June 30, 2014 would have been approximately $, or $ per share. This represents an immediate increase in net tangible book value of $ per share to existing stockholders and an immediate dilution in net tangible book value of $ per share to purchasers of shares in this offering.

The following table illustrates this per share dilution:

	Maximum Offering
Assumed public offering price per share	$
Net tangible book value per share as of June 30, 2014	$
Increase in net tangible book value per share attributable to new investors	$
Adjusted net tangible book value per share as of June 30, 2014, after giving effect to the offering	$
Dilution per share to new investors in the offering	$

The foregoing does not take into account:

- 20,501,138 shares of our common stock issuable upon the exercise of warrants outstanding with an exercise price of $0.0878;
- 23,541,738 shares of our common stock to be issued upon the vesting of restricted stock units issued pursuant to our 2014 Equity Incentive Plan;
- 9,041,737 shares available for future issuance and grants under our 2014 Equity Incentive Plan; and
- up to shares of common stock issuable upon the exercise of the warrants to be issued to the placement agent in connection with this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis is based on, and should be read in conjunction with our financial statements, which are included elsewhere in this prospectus. Management's Discussion and Analysis of Financial Condition and Results of Operations contains statements that are forward-looking. These statements are based on current expectations and assumptions that are subject to risk, uncertainties and other factors. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate," or "continue," and similar expressions or variations. Actual results could differ materially because of the factors discussed in "Risk Factors" elsewhere in this prospectus, and other factors that we may not know.

Background

We are a biopharmaceutical company that is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers. Our preliminary focus is on the development of therapies for skin, prostate and lung cancers in the U.S. market, with the first indication targeting basal cell carcinoma in patients with Gorlin Syndrome, a genetic disease also known as basal cell carcinoma nevus syndrome, which, among other conditions, causes the chronic formation of basal cell tumors. Our proposed therapy is based upon the use of a patented formulation of the currently marketed anti-fungal drug itraconazole.

We have developed, licensed and are seeking to acquire and/or license, intellectual property and know-how related to the treatment of cancer patients using itraconazole and have applied for patents to cover our inventions. We have exclusive rights in the U.S. to develop and to commercialize a specially formulated, patented version of itraconazole, known as SUBA-Itraconazole Capsules, for the treatment of human cancer via oral administration. SUBA-Itraconazole was developed and is licensed to us by our manufacturing partner Mayne Pharma. We believe that the dosing of oral capsules of SUBA-Itraconazole can affect the Hedgehog signaling pathway, a major regulator of many fundamental cellular processes, which, in turn, can impact the development and growth of cancer such as basal cell carcinoma.

We were founded under the name "Commonwealth Biotechnologies, Inc." in Virginia in 1992, and completed an initial public offering in October 1997. CBI previously provided, on a contract basis, specialized life sciences services to the pharmaceutical and biotechnology sector. On January 20, 2011, CBI filed a voluntary petition for bankruptcy. We began our current business in August 2013 as a Delaware corporation following the emergence of CBI from its voluntary bankruptcy proceedings.

Critical Accounting Policies and Estimates

Use of Estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

Revenue Recognition

We currently have no ongoing source of revenues. Any miscellaneous income is recognized when earned.

Cash and Cash Equivalents

We consider all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. At times, we may maintain cash balances in excess of Federal Deposit Insurance Corporation insured amounts.

Research and Development Expenses

Research and development costs are expensed in the period in which they are incurred and include the expenses paid to third parties who conduct research and development activities on our behalf.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2014-09, "Revenue from Contracts with Customers," which supersedes the revenue recognition requirements of Accounting Standards Codification ("ASC") Topic 605, "Revenue Recognition" and most industry-specific guidance on revenue recognition throughout the ASC. The new standard is principles-based and provides a five step model to determine when and how revenue is recognized. The core principle of the new standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The new standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. The new standard will be effective for us in the first quarter of the year ending December 31, 2017 and can be applied either retrospectively to all periods presented or as a cumulative-effect adjustment as of the date of adoption. Early adoption is not permitted. Wewill evaluate the impact of adoption of the new standard on our financial statements upon commencement of revenue generating activities.

Accounting for Enterprises in Reorganization

FASB ASC Topic 852—*Reorganizations* ("ASC Topic 852"), which is applicable to companies in Chapter 11, generally does not change the manner in which financial statements are prepared. However, it does require that the financial statements for periods subsequent to our predecessor's filing of the Chapter 11 petition distinguish transactions and events that are directly associated with the reorganization from the ongoing operations of the business. Revenues, expenses, realized gains and losses, and provisions for losses that can be directly associated with the reorganization and restructuring of the business must be reported separately as reorganization items in the statements of operations beginning in the quarter ending March 31, 2011. The balance sheet must distinguish prepetition liabilities subject to compromise from both those prepetition liabilities that are not subject to compromise and from post-petition liabilities. Liabilities that may be affected by a plan of reorganization must be reported at the amounts expected to be allowed by the applicable bankruptcy court, even if they may be settled for lesser amounts. In addition, cash flows from reorganization items must be disclosed separately in the statement of cash flows. We became subject to ASC Topic 852 effective on January 20, 2011, and segregated those items as outlined above for all reporting periods after such date. We officially emerged from bankruptcy on April 17, 2013, followed by the reincorporation merger and contribution of assets by Hedgepath, LLC (presently one of our principal stockholders), which satisfied the final condition to effectiveness of our reorganization plan. Accordingly, all pre-petition liabilities had been settled as of December 31, 2013, and there are no further reorganization items requiring recognition in the 2014 statement of operation.

Income Taxes

Deferred tax assets and liabilities are recognized for future tax consequences attributed to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and are measured using enacted tax rates that are expected to apply to the differences in the periods that they are expected to reverse. Management has evaluated the guidance relating to accounting for uncertainty in income taxes and has determined that we had no uncertain income tax positions that could have a significant effect on the consolidated financial statements for the six months ended June 30, 2014 or 2013.

Supply and License Agreement

Upon entering into our Amended and Restated Supply and License Agreementwith Mayne Pharma in June 2014,we issued 258,363 shares of our Series A Preferred Stock and a warrant to purchase 10,250,569 shares of common stockto Mayne Pharma. The fair value of the issued preferred shares and warrants has been accounted for as in-process research and development totaling approximately $1.9 million and is included in research and development expense for the quarter ended June 30, 2014.

For the Year Ended December 31, 2013 Compared to the Year Ended December 31, 2012

Chapter 11 Expenses. We recognized $117,324 in Chapter 11 expenses during the year ended December 31, 2013. Chapter 11 expenses consist solely of U.S. Trustee fees and legal fees relating to our bankruptcy filing. There was no such expense during the corresponding period in 2012.

Research and Development Expenses. We recognized $1,065,169 in research and development expenses during the year ended December 31, 2013. There was no such expense during the corresponding period in 2012. Research and development expenses consist of the in-process research and development purchased with the issuance of the preferred shares to Hedgepath, LLC, and salaries related to clinical trial design and regulatory activities.

General and Administrative Expenses. We recognized $817,316 and $560,670 in general and administrative expenses during the years ended December 31, 2013 and 2012, respectively. General and administrative expenses consist primarily of compensation and related costs for corporate administrative staff, facility expenditures, professional fees, consulting and taxes. This increase is primarily a result of officer and employee compensation, accounting and legal fees.

Interest Expense. We recognized $1,923 in interest expense during the year ended December 31, 2013. There was no such expense during the corresponding period in 2012.

Gain on Reorganization. We recognized an aggregate of $166,676 and $747,036 in gain on reorganization during the years ended December 31, 2013 and 2012, respectively. Gain on reorganization is associated with the final payments under the Chapter 11 reorganization plan.

For the three months ended June 30, 2014 compared to the three months ended June 30, 2013

Chapter 11 Expenses.We recognized $117,324 in Chapter 11 expenses during the three months ended June 30, 2013. There was no such expense during the corresponding period in 2014 as our bankruptcy proceedings concluded in 2013. Chapter 11 expenses consist solely of trustee fees and legal fees relating to CBI's bankruptcy filing.

Research and Development Expenses.We recognized $1,930,482 in research and development expenses during the three months ended June 30, 2014. There was no such expense during the corresponding period in 2013. Research and development expenses include $1,909,860 of purchased in-process research and development related to our supply and license agreement with Mayne Pharma, as well as salaries related to clinical trial design and regulatory activities.

General and Administrative Expenses.We recognized $185,182 and $286,256 in general and administrative expenses during the three months ended June 30, 2014 and 2013, respectively. General and administrative expenses consist of compensation and related costs for corporate administrative staff, facility expenditures, professional fees, consulting and taxes. The decrease is primarily a result of the accrual of officer and employee compensation in the prior year. There were no such accruals for the three months ended June 30, 2014.

Interest Expense. We recognized $24,994 in interest expense during the three months ended June 30, 2014, which includes approximately $18,000 in increased interest related to former employee notes resulting from extensions of such notes. There was no such expense during the corresponding period in 2013. Interest expense consists of interest accrued on notes payable.

Gain on Reorganization. We recognized $166,676 in gain on reorganization during the three months ended June 30, 2013. There was no such gain during the corresponding period in 2014. Gain on reorganization is associated with the final payments under the Chapter 11 reorganization plan.

Other Expense. We recognized $30,000 in other expense during the three months ended June 30, 2013. There was no such expense during the corresponding period in 2014. Other expense consists of fees paid under the terms of the approved CBI bankruptcy plan.

For the six months ended June 30, 2014 compared to the six months ended June 30, 2013

Chapter 11 Expenses.We recognized $117,324 in Chapter 11 expenses during the six months ended June 30, 2013. There was no such expense during the corresponding period in 2014 as our bankruptcy proceedings concluded in 2013. Chapter 11 expenses consist solely of trustee fees and legal fees relating to CBI's bankruptcy filing.

Research and Development Expenses.We recognized $1,955,807 in research and development expenses during the six months ended June 30, 2014. There was no such expense during the corresponding period in 2013. Research and development expenses include $1,909,860 of purchased in-process research and development related to our supply and license agreement with Mayne Pharma, as well as salaries related to clinical trial design and regulatory activities.

General and Administrative Expenses. We recognized $346,787 and $376,800 in general and administrative expenses during the six months ended June 30, 2014 and 2013, respectively. General and administrative expenses consist primarily of compensation and related costs for corporate administrative staff, facility expenditures, professional fees, consulting and taxes. This decrease is primarily a result of the accrual of officer and employee compensation in the prior year.There were no such accruals necessary for the six months ended June 30, 2014.

Interest Expense. We recognized $34,552 in interest expense during the six months ended June 30, 2014 which includes approximately $24,666 in increased interest related to the former employee notes resulting from extensions of such notes. There was no such expense during the corresponding period in 2013.

Gain on Reorganization. We recognized $166,676 in gain on reorganization during the six months ended June 30, 2013. There was no such gain during the corresponding period in 2014. Gain on reorganization is associated with the final payments under the Chapter 11 reorganization plan.

Liquidity and Capital Resources

As of June 30, 2014, we had approximately $270,000 cash on hand and commitments in the form of a note receivable for an additional $1,100,000 of capital from HPLLC. As of September 16, 2014, we had approximately $285,000 cash on hand and commitments in the form of a note receivable for an additional $700,000 of capital from HPLLC.

We will require additional financing in the near term in order to progress our business plan, and our failure to raise such funds could lead to the failure of our business in the near term. It is highly unlikely that any funds required during the next twelve months can be generated from our operations. Moreover, there can be no assurances given that additional funds will be available from external sources, such as debt or equity financing or other potential sources on commercially acceptable terms, or at all.

We intend to seek financing for our research and development, commercialization and distribution efforts and our working capital needs primarily through:

- securing proceeds from public and private financings and, potentially, other strategic transactions;
- partnering with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive upfront milestone and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing our product; and
- seeking government or private foundation grants which would be awarded to us to further develop our current and future anti-cancer therapies.

There is a risk that none of these or similar efforts will raise needed cash for us. As a result of the foregoing circumstances, there is substantial doubt about our ability to continue as a going concern. The financial statements included herein do not include any adjustments relating to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should we be unable to continue as a going concern.

Contractual Obligations and Commercial Commitments

Our non-cancellable contractual obligations as of June 30, 2014 are as follows:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Notes payable	$102,420	$102,420	$ —	$ —	$ —
Employment agreements	576,475	193,200	383,275		
Total contractual cash obligations	$678,895	$295,620	$383,275	$ —	$ —

BUSINESS

Overview

We are a biopharmaceutical company that is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers. Our preliminary focus is on the development of therapies for skin, prostate and lung cancers in the U.S. market. Our proposed therapy is based upon the use of a patented formulation of the currently marketed anti-fungal drug itraconazole.

Following a meeting between our management and representatives of the FDA in August 2014, we anticipate submitting an IND application for the use of our product candidate to treat basal cell carcinoma in patients with Gorlin Syndrome, a genetic disease also known as basal cell carcinoma nevus syndrome, which, among other conditions, causes the chronic formation of basal cell tumors.

We have exclusive rights in the U.S. to develop and to commercialize a specially formulated, patented version of itraconazole, known as SUBA-Itraconazole, for the treatment of human cancer via oral administration. "SUBA technology" (which stands for "super bioavailability") is designed to improve the bioavailability of orally administered drugs that are poorly soluble. In studies conducted by Mayne Pharma relating to SUBA-Itraconazole's anti-fungal application, SUBA-Itraconazole has demonstrated improved absorption and significantly reduced variability compared to the branded and generic forms of itraconazole in human studies. We believe this technology is well-suited for the exploration of the potential anti-cancer effects of itraconazole. SUBA-Itraconazole was developed and is licensed to us by our manufacturing partner Mayne Pharma under a Supply and License Agreement, originally dated September 3, 2013, and most recently amended and restated on June 24, 2014. We refer to this agreement herein as the Supply and License Agreement. Mayne Pharma is an Australian specialty pharmaceutical company that develops and manufactures branded and generic products, which it distributes directly or through distribution partners and also provides contract development and manufacturing services. In addition to being our licensor and supply partner, under the License and Supply Agreement and related agreements, Mayne Pharma holds a significant minority equity stake in our company and holds important rights with respect to our company, such as the right to appoint a member to our Board of Directors. See "—Manufacturing and Product Supply and Relationship with Mayne Pharma" and "Certain Relationships and Related Party Transactions" below for more information.

Based on existing scientific data, including from in vitro, animal and human studies, we believe that itraconazole affects the Hedgehog signaling pathway in cells, a major regulator of many fundamental cellular processes, which could in turn impact the development and growth of certain cancers. Itraconazole is approved for and extensively used to treat anti-fungal infections and has a significant history of safe and effective use in humans. We have developed, licensed and are seeking to acquire and/or license, intellectual property and know-how related to the treatment of cancer patients using itraconazole and have applied for patents to cover our inventions.

Our regulatory strategy is driven by the so called 505(b)(2) regulatory pathway, under which a drug (in our case, itraconazole) that has already been approved for use in humans in the United States by the FDA) is developed for one or more new medical indications (in our case, as an anti-cancer agent). Due to the history of safe and efficacious use of itraconazole in humans for anti-fungal applications, we believe the 505(b)(2) pathway will be available to us, which may create the potential for significantly reducing the risk and time to achieve FDA approval of our cancer therapy.

The Hedgehog Pathway

The Hedgehog signaling pathway is a major regulator of many fundamental cellular processes in vertebrates, including primarily at the embryonic stage of development but also as it relates to stem cell maintenance, cell differentiation, tissue polarity and cell proliferation. Based on published third party research, we believe that inhibiting the Hedgehog pathway could delay or possibly prevent the development of certain cancers in patients. Research has shown that activation of the Hedgehog pathway can lead to the formation of cancerous tumors (a process known as tumorigenesis) such as the most common form of skin cancer known as basal cell carcinoma. A variety of other human cancers, including brain, gastrointestinal, lung, breast and prostate cancers, also demonstrate inappropriate activation of this pathway. Hedgehog signaling from the tumor to the surrounding cell structures has been shown to sometimes promote further tumorigenesis as well. This pathway has also been shown to regulate proliferation of cancer stem cells and to increase tumor invasiveness.

We believe that the targeted inhibition of Hedgehog signaling may be effective in the treatment and prevention of many types of human cancers. We also believe that the discovery and synthesis of specific Hedgehog pathway inhibitors may have significant clinical implications regarding the development of novel cancer therapies. Several synthetic Hedgehog antagonists are now being studied, some of which are undergoing clinical evaluation. The orally available drug, Erivedge® (generic name vismodegib, developed by Genentech, Inc., a subsidiary of Roche), is the first Hedgehog inhibitor based-therapy that has been approved for treatment of advanced stages of basal cell carcinoma by the FDA.

Repurposing Itraconazole for Treating Cancer

We are implementing clinical and regulatory plans to enable the repurposing of itraconazole for the treatment of a variety of cancers. This strategy (using the so-called 505(b)(2) regulatory pathway) is intended to significantly reduce the risk and time to potential FDA approvals for marketing in the United States. Initial target applications include therapies for prostate, lung and skin cancers, among others.

Itraconazole appears to have notable anti-cancer effects by one or more independent or synergistic mechanisms, some of which are not clearly understood and continue to be the subject of ongoing research. These anti-cancer effects have been demonstrated in various animal models and subsequently in human studies conducted by third parties over the last few years, all of which are the basis of our interest in the clinical development of itraconazole for treatment of human cancers.

We believe that our development of SUBA-Itraconazole as an anti-cancer therapy may lead to its use as an inhibitor of the Hedgehog pathway, thereby retarding the progression of cancer.

In animal models, itraconazole has also demonstrated an anti-angiogenic effect (i.e., inhibiting the formation of new blood vessels), which may be important in controlling the proliferation of cancerous cells and tumors in humans based upon its interaction with certain cell-based growth factors. Itraconazole also appears to induce changes related to the mTOR pathway, an important regulator of cell growth, proliferation and survival which, when unregulated, can also lead to cancer.

We believe that the use of SUBA-Itraconazole to treat each of our target cancer patient populations has the potential to benefit from various FDA programs designed to expedite the approval process.

Basal Cell Carcinoma

The first cancer indication we expect to study is basal cell carcinoma (BCC) in patients with Gorlin Syndrome, a condition also known as basal cell carcinoma nevus syndrome (or BCCNS), which patients develop numerous BCC tumors on an on-going basis.Patients with BCCNS have a mutation of the PATCHED (PTCH1) suppressor gene, which normally inhibits a protein known as SMOOTHENED (SMO) which in turn controls the Hedgehog signaling pathway. Vismodegib and other Hedgehog pathway inhibitors bind to the transmembrane protein SMO and inhibit its function to overcome the PTCH1 mutation. Itraconazole also inhibits SMO, but through a mechanism which affects its translocation, which may be the reason, as evidenced in human testingof itraconazole for BCC, it has demonstrated a more favorable toxicity profile than vismodegib.

Lung Cancer

Patients with advanced non-squamous non-small cell lung cancer (most often caused by cigarette smoking) have few options when considering therapies to extend survival. With a median survival of only 8-10 months while on approved chemotherapy regimens, we believe that new therapies are needed. We believe that the pre-clinical data and human data reported in 2013on the use of itraconazole in conjunction with chemotherapy reflects positively on the use of itraconazole as an anti-cancer therapy for this form of lung cancer. If these data prove to be applicable to human treatment by improving progression free survival and/or overall survival, while dosing SUBA-Itraconazole in combination with first-line chemotherapy therapy (the combination of chemotherapy drugs Pemetrexed and Cisplatin), the treatment may qualify for one or more FDA accelerated programs, such as a breakthrough therapy or fast track status.

Prostate Cancer

Itraconazole has already been tested as a treatment for men with metastatic castrate resistant prostate cancer in a multi-institutional Phase II trial led by Johns Hopkins University and completed in 2011 and published in 2013, which showed that, at a specified dose, there was a significant correlation to slowing the progression of cancer and extending survival. The study showed a well-defined correlation between the down-regulation of Hedgehog signaling, via biomarker studies, and improvements in PSA progression and progression free survival. Based on those encouraging results in metastatic disease, we are planning to test SUBA- Itraconazole in high-risk men with non-metastatic prostate cancer (who are castrate resistant, either based upon drug therapy or surgery) to study the effect of SUBA-Itraconazole therapy in delaying metastases. There is no currently approved drug therapy for these patients and yet they are treated with drugs designed for metastatic disease on annon-promoted basis. We believe this is a significant opportunity for us since we intend to offer a low toxicity, non-androgen dependent small molecule therapy to a very large population of patients. Therapy with SUBA-Itraconazole may offer great promise for delaying the use of, and associated side-effects due to, those Androgen Deprivation Therapy (ADT) Drugs which are formulated to lower testosterone levels but are intended for metastatic disease treatment.

Our Potential Market

The following table depicts our current estimate of the total available market opportunity for our proposed anti-cancer therapies based upon independent market research, scientific and industry publications and management's knowledge of the U.S. oncology market. Our estimates (including estimated product pricing) are based on current assumptions and are subject to change.

HedgePath Pharmaceuticals, Inc. – Summary U.S. Market Opportunity

Cancer	Therapy Indication	Potential for SUBA-Itraconazole	Target Patient Population	U.S. Total Available Market
Skin(1)	Patients with BCC (basal cell carcinoma) lesions First indication: BCC tumors in Gorlin Syndrome Patients requiring MOHs surgery Follow-on Indication: Patients with BCC facial lesions pending MOHs or other surgical procedures	Less toxic therapy than vismodegib for Gorlin Patients to delay MOHs surgeries; low toxicity therapy to delay or minimize surgical intervention for facial BCC tumors	9,000 Gorlin patients needing chronic BCC therapy; 65,000 BCC patients pending surgical treatment for facial tumors that require excision and potential plastic surgery	$900M based upon HedgePath estimates of ~ $4K-$5K monthly cost of therapy for target populations
Lung(2)	Patients with advanced non-squamous cell, non small cell lung cancer (NSCLC) who will be placed on Cisplatin/Pemetrexed IV Therapy	Improve the current median 8-10 month survival achieved with best supportive care	56,000 men and women with late-stage disease on chemotherapy treatment	$1.7 B based on HedgePath estimates of ~ $4K-$5K monthly cost of therapy
Prostate(3)	Patients with non metastatic castrate resistant prostate cancer (NMCRPC) and rising PSA levels on "off-label" androgen deprivation therapy (ADT)	Delay the progression to metastatic disease while preventing or reducing the use of ADT and its associated side-effects	45,000 high-risk men with prostate cancer which may lead to metastases of the bone	$1.5B based on HedgePath estimates of ~ $4K-$5K monthly cost of therapy

References:

(1) *J Am Academy Dermatology, 2006; Skin Cancer Foundation, 2009; International Medicine News, 2011; Seeking Alpha, 2012; BCCNS Support Organization 2014*

(2) *STATS MGU, 2009; Global Industry Analysts, 2010; BMC Health Services, 2011; World Health Organization, 2011; Cost of Treating Lung Cancer, 2012; National Center for Biotechnology Information, 2012*

(3) *J. Urology, 2003; Oncology, 2004; J. Clinical Oncology, 2011; Medscape, 2012; Landes Bioscience, 2012*

Our Strategy

Our goal is to be a leader in the development and commercialization of SUBA-Itraconazole-based therapeutics for the treatment of cancer patients. We believe that we can accomplish this goal by implementing the following key elements of our business strategy:

- *Rapidly Advance the Clinical Development of Our Therapies.* With the history of safe use of itraconazole in humans for anti-fungal indications, we believe we can bypass each of the required pre-clinical animal studies for toxicity and Phase I human trials to establish safety, and therefore move directly into Phase II human trials, in reliance on the 505(b)(2) pathway. We intend to apply for Investigational New Drug (or IND) approval in September 2014 for SUBA-Itraconazole for the treatment of cancer as a disease category, and thereafter file individualized clinical trial protocols for each of our target cancer indications in order to have the ability to initiate our clinical trials in parallel.

- *Seek FDA Programs to Expedite Drug Approvals.* The FDA has various programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions. These expedited programs help ensure that therapies for serious conditions are available as soon as it can be concluded that the therapies' benefits justify their risks, taking into account the seriousness of the condition and the availability of alternative treatments. These programs include breakthrough therapy designation, fast track designation, accelerated approval, and priority review. We believe that SUBA-Itraconazole for the treatment of cancer may qualify for one of these designations, which could help expedite the regulatory review process.

- *Commercialize and Market with Exclusivity.* We are currently preparing for the clinical testing of SUBA-Itraconazole for treatment of cancer in order to later seek FDA approvals based upon its efficacy for this new indication. We have developed specific clinical trial designs to address different forms of cancer in order to pursue New Drug Application (or NDA) approvals for multiple indications. Further, we believe SUBA-Itraconazole can be commercialized in a way that maximizes benefits for cancer patients, based on our specific therapy regimens, while eliminating generic substitution and providing us with market exclusivity protections through our intellectual property rights.

We intend to finance our research and development, commercialization and distribution efforts and our working capital needs primarily through:

- partnering with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive upfront milestone and royalty payments;
- licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing our product to augment their product profile in the treatment of cancers;
- receiving government or private foundation grants which would be awarded to us to further develop our current and future anti-cancer therapies; and
- securing proceeds from public and private financings and other strategic transactions.

Background on Cancer

Cancer is a heterogeneous group of diseases characterized by uncontrolled cell division and growth. Cancerous cells that arise in the lymphatic system and bone marrow are referred to as hematological tumors. Cancer cells that arise in other tissues or organs are referred to as solid tumors. Researchers believe that exposure to some chemicals, viruses and various forms of radiation can cause genetic alterations that cause cancer. Genetic predispositions also can increase the risk of cancer in some people.

Cancer is the second leading cause of death in the United States, exceeded only by heart disease. The American Cancer Society estimates that in 2013 there will be approximately 1.6 million new cases of cancer and approximately 580,000 deaths from cancer in the United States.

The most common methods of treating patients with cancer are surgery, radiation and chemotherapy. A cancer patient often receives treatment with a combination of these methods. Surgery and radiation therapy are particularly effective in patients in whom the disease is localized (not spread beyond the initial site of disease). Physicians generally use systemic drug therapies in situations in which the cancer has spread beyond the primary site or cannot otherwise be treated through surgery. The goal of chemotherapy is to damage and kill cancer cells or to interfere with the molecular and cellular processes that control the development, growth and survival of cancer cells or tumors. In many cases, drug therapy entails the administration of several different drugs in combination. Over the past several decades, drug therapy has evolved from non-specific drugs that damage both healthy and cancerous cells, to drugs that target specific molecular pathways involved in cancer and more recently to therapeutics that target the specific oncogenic “drivers” of cancer.

Cytotoxic Chemotherapies. The earliest approach to pharmacological cancer treatment was to develop drugs, referred to as cytotoxic drugs, which kill rapidly proliferating cancer cells through non-specific mechanisms, such as disrupting cell metabolism or causing damage to cellular components required for survival and rapid growth. While these kinds of drugs have been effective in the treatment of some cancers, many unmet medical needs for the treatment of cancer remain. Also, cytotoxic drug therapies act in an indiscriminate manner, acting upon the metabolism of healthy as well as cancerous cells. Due to their mechanism of action, many cytotoxic drugs have a narrow dose range above which the toxicity causes unacceptable or even fatal levels of damage and below which the drugs are not effective in eradicating cancer cells.

Targeted Therapies. The next approach to pharmacological cancer treatment was to develop drugs, referred to as targeted therapeutics, that target specific biological molecules in the human body that play a role in rapid cell growth and the spread of cancer. Targeted therapeutics include vascular disruptors, also referred to as angiogenesis inhibitors, which prevent the formation of new blood vessels and restrict a tumor’s blood supply. Other targeted therapies affect cellular signaling pathways that are critical for the growth of cancer. While these drugs have been effective in the treatment of some cancers, most do not address the underlying cause of the disease. These drugs focus on inhibiting processes that help the cancer cell survive, but not the oncogenes that are the drivers or cause of the cancer itself.

Oncogenic Therapies. A more recent approach to pharmacological cancer treatment is to develop drugs that affect the drivers that cause uncontrolled growth of cancer cells because of a specific genetic alteration. In some cases, these agents were identified as therapeutics without knowledge of the underlying genetic change causing the disease. To date, the shortcoming of this research approach has been that it often follows a conventional trial and error approach to drug discovery. In this approach, clinical development involves the treatment of large populations from which a defined subpopulation that responds to treatment is identified. As a result, this approach can be time-consuming and costly, with success often uncertain. Another major concern of these newly discovered drugs, some of which have been recently approved, is that resistance to them occurs as the cancer finds new ways to circumvent the genetic pathway.

The Itraconazole Approach to Treating Cancer

We are focusing our developments on Hedgehog pathway inhibitor therapeutics for patients with certain cancers, including skin, lung and prostate cancers. Our initial product candidate is itraconazole, which has exhibited anti-cancer properties in human trials and therefore, we believe has compelling evidence as a potential treatment for cancer in humans. We have obtained from Mayne Pharma exclusive U.S. rights to develop and to commercialize SUBA-Itraconazole, a patented, more bioavailable formulation of the currently marketed drug itraconazole, for the treatment of human cancer via oral administration.

Background of Itraconazole. Itraconazole is FDA-approved for and used to treat serious fungal or yeast infections. This medicine works by killing the fungus or yeast and preventing its growth. Itraconazole is a prescription based medication, available as an IV solution, oral liquid, capsule or tablet.

*Cancer and Hedgehog Inhibitors.*The Hedgehog (also known as Hh) proteins comprise a group of secreted proteins that regulate cell growth, differentiation and survival. They are involved in organogenesis (the formation of organs), and have been shown to promote adult stem cell proliferation. Inappropriate activation of the Hh signaling pathway has been implicated in the development of several types of cancers including prostate, lung, pancreas, breast, brain and skin. Hedgehog pathway inhibitors are a relatively new class of therapeutic agents that act by targeting the proteins involved in the regulation of the Hh pathway. Many of these newly discovered inhibitors are currently undergoing preclinical testing and some have entered clinical studies as anti-cancer agents for a variety of cancers. Vismodegib has been approved for treatment of locally advanced and metastatic basal cell carcinoma in early 2012.

Similarly, itraconazole has also been shown to suppress growth of brain tumors in animal models. It has also been shown to have anti-cancer effects in basal cell carcinoma, lung cancer and prostate cancer in human clinical trials. Itraconazole acts as a SMO (a protein receptor of the Hh pathway) antagonist (blocker), in a manner distinct from its anti-fungal activity which targets a compound found in fungi and yeast known as ergosterol (a steroid found in the cell walls of fungi and yeast that functions in a fashion similar to cholesterol in humans) as well as having potential anti-angiogenic properties.

Intellectual Property

We strive to protect the intellectual property that we believe will be important to our business, including seeking our own patent protection (or seeking licenses to patents) intended to cover the composition of matter of our product candidate, its methods of use, related technology and other inventions that are important to our business.

In addition to the key intellectual property we have exclusively licensed in the United States from Mayne Pharma as described below, as part of our emergence from bankruptcy in August 2013, we acquired by way of contribution from Hedgepath, LLC the following two provisional patents related to Hedgehog pathway inhibitors via an assignment of patents underlying these provisional patents from each of Dr. Frank E. O'Donnell, Jr. our Executive Chairman and director, and Nicholas J. Virca, our President and Chief Executive Officer:

- U.S. Provisional Patent Application 61-831,122, "Prostate-Specific Antigen as Biomarker for Hedgehog Pathway Inhibitor Treatment and Prognostic Monitoring of Prostate Cancer" (previously assigned to Hedgepath, LLC by Dr. Frank E. O'Donnell, Jr. and Nicholas J. Virca, as inventors).
- U.S. Provisional Patent Application 61-813,823, "Treatment and Prognostic Monitoring of Cancer Using Hedgehog Pathway Inhibitors" (previously assigned to Hedgepath, LLC by Dr. Frank E. O'Donnell, Jr. and Nicholas J. Virca, as inventors).

Under United States patent law, a provisional application is a legal document filed in the United States Patent and Trademark Office (or USPTO), that establishes an early filing date, but which does not mature into an issued patent unless the applicant files a regular non-provisional patent application within one year, which we are currently working on. A provisional application includes a specification, i.e. a description, and drawing(s) of an invention but does not require formal patent claims, inventors' oaths or declarations or any information disclosure statement. A provisional application can establish an early effective filing date in one or more continuing patent applications later claiming the priority date of an invention disclosed in earlier provisional applications by one or more of the same inventors.

Additionally, the following patent application, filed by Hedgepath, LLC and dated February 5, 2014 was received by the USPTO on March 10, 2014 and also assigned to us: US Patent Application Serial # 14/173,588, "Treatment and Prognostic Monitoring of Proliferation Disorders Using Hedgehog Pathway Inhibitors" (assigned to HedgePath Pharmaceuticals, Inc., Dr. Frank E. O'Donnell, Jr and Nicholas J. Virca, as inventors).

We also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our viability as a company (including our ability to test, develop and ultimately commercialize itraconazole for the treatment of cancer) will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, methods, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also will rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the field of anti-cancer therapy.

A third party may hold intellectual property, including patent rights, which are important or necessary to the development of our products or therapies. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products or therapies, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. For example, some of the possible formulations of itraconazole include components covered by patents held by third parties. Although we believe that licenses to these patents are available from these third parties on commercially reasonable terms, if we were not able to obtain a license, or were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

We also plan to continue to expand our intellectual property estate by filing patent applications directed to dosage forms, methods of treatment, therapies for other cancers and additional Hedgehog inhibitor compounds and their derivatives.

Manufacturing and Product Supply and Relationship with Mayne Pharma

We are in the early stages of development and thus we do not have any production facilities or manufacturing personnel. We currently have a supply and license agreement in place with Mayne Pharma for the supply of and U.S. rights to Mayne Pharma's patented formulation of itraconazole, SUBA-Itraconazole. The agreement provides for the supply to us of specially formulated capsules of SUBA-Itraconazole, manufactured by Mayne Pharma under cGMP (current good manufacturing practice) standards, for use by us in our anticipated clinical trials, and for the future exclusive commercial supply following FDA approvals, if obtained.

Pursuant to the Supply and License Agreement, which was originally entered into on September 3, 2013 and most recently amended and restated on June 24, 2014, Mayne Pharma is obligated to: (i) supply us with its patented formulation of SUBA-Itraconazole in a particular dose formulation for the treatment of human patients with cancer via oral administration (with the initial areas of investigation being prostate, lung and skin cancer) in the United States, (ii) provide us with an exclusive license to perform specified development activities and to commercialize SUBA-Itraconazole for the treatment of cancer via oral administration in the United States and (iii) participate in a joint development committee (or JDC) with us to clinically develop SUBA-Itraconazole for the treatment of cancer in the United States. The Supply and License Agreement may be terminated by Mayne Pharma if we fail to achieve regulatory approval to commercialize SUBA-Itraconazole in the U.S. by March 31, 2017, if we breach any provision of our June 2014 Equity Holders Agreement or Purchase Agreement with Mayne Pharma, if we materially breach the Supply and License Agreement and do not cure such breach within a specified time period, or if either party files for bankruptcy or insolvency proceedings.

Pursuant to the Supply and License Agreement, we will develop and exploit SUBA-Itraconazole through a development plan which will be authorized by the JDC and updated as necessary. We cannot make changes to the development plan without Mayne Pharma's consent. The license granted to us under the Supply and License Agreement may only be assigned or sub-licensed with the prior approval of Mayne Pharma. In addition, in support of the exclusive nature of the Supply and License Agreement, during the term, Mayne Pharma is prohibited from directly or indirectly importing, promoting, marketing, distributing or selling SUBA-Itraconazole for the treatment of cancer in the United States. If any other form of the SUBA-Itraconazole manufactured by Mayne Pharma is sold as a result of any non-promoted use, we shall be entitled to a royalty on such non-promoted sales. Further, during the term of and for a period following the term of the Supply and License Agreement, we may not develop products that are competitive with SUBA-Itraconazole for the treatment of cancer.

Under the Supply and License Agreement, we are responsible for obtaining all of our requirements for SUBA-Itraconazole from Mayne Pharma, including for use in clinical trials, importation, promotion, marketing, sale and distribution in the United States. We and Mayne Pharma have established certain minimum floor prices that we must pay per unit of SUBA-Itraconazole and minimum order quantities for SUBA-Itraconazole. In addition, the agreement provides for certain annual minimum order quantities for SUBA-Itraconazole, and, if such quantities are not met, we must pay the shortfall or Mayne Pharma may terminate the agreement.

Any intellectual property created by us, either on our own or jointly with Mayne Pharma, relating to SUBA-Itraconazole for the treatment of cancer will be owned by us, except that we have granted Mayne Pharma an exclusive, perpetual, irrevocable, sublicensable, royalty free license to copy and exploit such developed intellectual property outside of the United States.

On June 24, 2014, we and Mayne Pharma, along with Nicholas J. Virca, our President and Chief Executive Officer, Frank E. O'Donnell, Jr., M.D., our Executive Chairman, and Hedgepath, LLC, a Florida limited liability company and the then majority stockholder of our company which is controlled by Black Robe Capital LLC, of which Dr. O'Donnell is the manager, consummated a series of related transactions to fulfill certain conditions of the Supply and License Agreement. In connection therewith, we and Mayne Pharma entered into an Amended and Restated Supply and License Agreement. In addition, on June 24, 2014, in fulfillment of one of the conditions under the Supply and License Agreement, we entered into a Securities Purchase Agreement with Mayne Pharma (which we refer to as the Mayne Purchase Agreement). Pursuant to the terms of the Mayne Purchase Agreement, we issued to Mayne Pharma (i) 258,363.280 shares of our Series A Preferred Stock, and (ii) a warrant to purchase 10,250,569 shares of our common stock. The shares of Series A Preferred Stock converted into 87,843,897 shares of common stock on August 14, 2014. Such warrant has an exercise price of $0.0878 per share and may be exercised at any time, from time to time, by Mayne Pharma prior to the expiration on June 24, 2019. As a result of the Mayne Purchase Agreement, Mayne Pharma owns approximately 40% of our equity securities on a fully diluted basis. See "Certain Relationships and Related Party Transactions" for further information.

Sales and Marketing

We are in the early stages of development and thus have not yet established a sales, marketing or product distribution infrastructure because our product candidate is still in clinical development. We may either license commercialization rights to our product candidate to larger third party partners, who will be responsible for sales, distribution and marketing efforts, or we may (assuming adequate resources are available) retain commercial rights for our product candidate, in which case we would seek to access the oncology market through a focused, specialized sales force of our own or in conjunction with a marketing partner under a co-promotion agreement.

Competition

The pharmaceutical industry is highly competitive and subject to rapid and substantial regulatory and technological changes. Developments by others may render our itraconazole therapies, or any proposed product candidates and formulations under development, non-competitive or obsolete, or we may be unable to keep pace with anti-cancer therapy developments or other market factors. Anti-cancer therapy competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

Below are some examples of companies seeking to develop potentially competitive anti-cancer therapies or related products, though the examples are not all-inclusive. Many of these entities have significantly greater research and development capabilities than do we, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. In addition, acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' research, financial, marketing, manufacturing and other resources. Such potential competitive anti-cancer therapies may ultimately prove to be safer, more effective or less costly than any product candidates that we are currently developing or may be able to develop. Additionally, our competitive position may be materially affected by our ability to develop or commercialize our drugs and technologies before any such competitor. Other external factors may also impact the ability of our products to meet expectations or effectively compete, including pricing pressures, healthcare reform and other government interventions.

The chart below lists products or products in development that we believe may compete directly with our proposed itraconazole therapy:

Names	Company	Description	Status
Taxotere®docetaxel	Sanofi-Aventis	Anti-tumor agent for MCRPC and late-stage NSCLC	Approved 2004; and new generics
Jevtana®cabazitaxel	Sanofi-Aventis	MCRPC following docetaxel failure	Approved 2010
Provenge®sipuleucel-T	Dendreon	Immunotherapy for asymptomatic MCRPC	Approved 2010
Zytiga®aberaterone	Janssen Biotech	Androgen synthesis inhibitor for MCRPC	Approved 2011
Xtandi®enzalutamide	Astellas	Androgen receptor inhibitor for MCRPC previously on docetaxel	Approved 2012
Erivedge®vismodegib	Roche Genentech	Hedgehog inhibitor for advanced BCC and Gorlin Syndrome	Approved 2012
LDE225 - erismodegib	Novartis	Hedgehog inhibitor for advanced BCC and Gorlin Syndrome	Late stage clinical trials
Avastin®bevacizumab	Genentech	Angiogenesis inhibitor for NSCLC except squamous cell lung cancer	Approved for multiple cancers since 2004
Gemzar® gemcitabine	Lilly	Cytotoxic chemotherapy agent for NSCLC in combination with platinum drugs	Approved for multiple cancers since 1996
Trexall® methotrexate	Teva	Antimetabolite therapy to slow cancer cell growth	Approved before 1984
Tarceva®erlotinib		Epidermal growth factor inhibitor treatment for NSCLC - maintenance therapy after chemo or metastatic disease after chemo	Approved in 2013
Xalkori®crizotinib	Pfizer	Selective inhibitor for late-state NSCLC patients who express the ALK gene	Approved in 2011
Gilotrif®afatinib	Boehringer	NSCLC with mutations in EGFR	Approved 2013
Zykadia® certinib	Novartis	ALK-positive metastatic NSCLC for patients who progressed on Xalkori	Approved 2014

Abbreviations: MCRPC (metastatic castrate resistant prostate cancer), NSCLC (non-small cell lung cancer), BCC (basal cell carcinoma).

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending new drug applications, or NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an independent institutional review board (or IRB) at each clinical site before each trial may be initiated;
- performance of human clinical trials, including adequate and well-controlled clinical trials, in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices (or cGMP) and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, as well as satisfactory completion of an FDA inspection of selected clinical sites to determine GCP compliance; and
- FDA review and approval of the NDA.

Preclinical Studies. Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

We hope to avoid pre-clinical studies or any Phase I studies to demonstrate safety based on the fact that itraconazole has an established history of safe and effective use in humans for anti-fungal indications, and human data are already available and published regarding use of itraconazole in humans for anti-cancer indications, such as basal cell carcinoma, lung cancer and prostate cancer, at the Phase II level.

Clinical Trials. Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB (institutional review board) at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must continue to oversee the clinical trial while it is being conducted. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase I, the drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness. In Phase II, the drug typically is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. In Phase III, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the drug has been associated with unexpected serious harm to patients. As mentioned previously, we intend to move directly into Phase II trials with SUBA-Itraconazole for our targeted anti-cancer indications based upon the previous, well-established safety profile of itraconazole use in humans for treatment of anti-fungal indications and based upon the previous human data regarding the use of itraconazole for anti-cancer indications such as basal cell carcinoma, lung cancer and prostate cancer.

Marketing Approval. Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product’s chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act (or PDUFA) guidelines that are currently in effect, the FDA has agreed to certain performance goals regarding the timing of its review of an application.

The FDA also may require submission of a risk evaluation and mitigation strategy (or REMS) plan to mitigate any identified or suspected serious risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. We believe that a REMS program, which includes intellectual property related to SUBA-Itraconazole and itraconazole, and the specific use of SUBA-Itraconazole for anti-cancer indications, may likely provide additional protection of our proposed therapies from generic substitution.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA typically refers a question regarding a novel drug to an external advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCP.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including

Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS (Risk Evaluation Mitigation Strategy) which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Special FDA Expedited Review and Approval Programs. The FDA has various programs, including fast track designation, accelerated approval, priority review and breakthrough designation, that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures. To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors.

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. These six and ten month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We believe that we may qualify for one or more of these expedited approvals since our itraconazole anti-cancer therapies offer significant improvements in therapy for all of our targeted anti-cancer indications should they be approved by FDA.

Post-Approval Requirements. Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase IV clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications, pharmaceutical companies generally are required to promote their drug products only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (or PDMA), which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Federal and State Fraud and Abuse and Data Privacy and Security Laws and Regulations. In addition to FDA restrictions on marketing of pharmaceutical products, federal and state fraud and abuse laws restrict business practices in the biopharmaceutical industry. These laws include anti-kickback and false claims laws and regulations as well as data privacy and security laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting some common activities from prosecution, the exemptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

The reach of the Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (or collectively PPACA), which, among other things, amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. PPACA also created new federal requirements for reporting, by applicable manufacturers of covered drugs, payments and other transfers of value to physicians and teaching hospitals.

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses. The federal Health Insurance Portability and Accountability Act of 1996 (or HIPAA) created new federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act (or HITECH) and its implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Coverage and Reimbursement. The commercial success of our product candidate and our ability to commercialize any approved product candidate will depend in part on the extent to which governmental authorities, private health insurers and other third party payors provide coverage for and establish adequate reimbursement levels for our therapeutic product candidates and related companion diagnostics. Government health administration authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the United States, government authorities and third party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

Third party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for medical products. For example, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products and product candidates or exclusion of our products and product candidates from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third party coverage or adequate reimbursement for our product candidate in whole or in part.

Impact of Healthcare Reform on Coverage, Reimbursement, and Pricing. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (or MMA) imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Part D plans include both standalone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, any negotiated prices for our future products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from Medicare Part D may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third party payors do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidates, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The United States is considering enacting or has enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including, most recently, PPACA, which became law in March 2010 and substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, the PPACA establishes an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit the prices we are able to charge for our product candidates, once approved, or the amounts of reimbursement available for our product candidates once they are approved.

Exclusivity and Approval of Competing Products

Hatch-Waxman Patent Exclusivity. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA, or 505(b)(2) NDA.

Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths, dosage form and route of administration as the listed drug and has been shown to be bioequivalent through *in vitro* or *in vivo* testing or otherwise to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug. 505(b)(2) NDAs generally are submitted for changes to a previously approved drug product, such as a new dosage form or indication. The 505(b)(2) regulatory pathway may be available for our proposed application of itraconazole as an anti-cancer therapy.

The ANDA or 505(b)(2) NDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable, or will not be infringed by the new product.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except when the ANDA or 505(b)(2) NDA applicant challenges a listed drug. A certification that the proposed product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA.

The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of notice of the Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

Hatch-Waxman Non-Patent Exclusivity. Market and data exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications for competing products. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA or 505(b)(2) NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application or supplement. Three-year exclusivity may be awarded for changes to a previously approved drug product, such as new indications, dosages, strengths or dosage forms of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan Drug Exclusivity. The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals annually in the United States. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug that is approved for the orphan drug designated indication is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. We intend to seek orphan drug designation and exclusivity for our product candidate which may include treatment of basal cell carcinoma in patients with Gorlin syndrome and stage IV non-squamous, non-small cell lung cancer.

Foreign Regulation

Although it is not presently our intention to seek approval of our product candidate outside of the United States, in the future we may do so, either directly or in conjunction with a marketing partner. In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. This would be the responsibility of one or more of our potential marketing partners. We do however intend to include sites outside the United States for our clinical trials in order to be able to recruit more patients for testing at a greater number of locations and in less time than if we were to focus only on US-based sites. For example, in the European Union, we would need to obtain authorization of a clinical trial application (or CTA) in each member state in which we intend to conduct a clinical trial. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Litigation

In October 2012, Andrew Chien, an alleged stockholder of our predecessor, CBI, filed suit in Connecticut state court (later removed to the United States District Court for the District of Connecticut, also referred to as the CT District Court) against CBI, Dr. Richard J. Freer (a director and officer of CBI), and the law firm LeClairRyan alleging certain violations of securities laws and breaches of fiduciary duty.In October 2012, the CT District Court in the this case entered an Order dismissing Mr. Chien’s claims without prejudice on account of CBI’s pending Chapter 11 bankruptcy.Mr. Chien then filed various motions in response to the CT District Court’s decision dismissing the claims asserted against Dr. Freer and LeClairRyan, including a motion for reconsideration. On May 29, 2014, the presiding judge issued several orders. The CT District Court granted Mr. Chien’s request that he be allowed to proceed with the fifth and sixth claims he asserted against CBI in his complaint, namely (i) a claim for relief entitled “Securities Fraud and Fiduciary Duty Violation against CBI” and (ii) a claim for relief entitled “Fiduciary Duty violation against CBI”. A related scheduling order provided that CBI had until June 20, 2014 to answer or otherwise respond to the complaint. We have retained LeClairRyan to serve as CBI’s counsel in the case. On June 20, 2014, LeClairRyan filed on CBI’s behalf a motion to dismiss seeking a dismissal with prejudice of Mr. Chien’s claims. LeClairRyan also filed on CBI’s behalf a motion to stay discovery. On August 5, 2014, the CT District Court granted CBI’s motion to stay discovery. The parties are now awaiting a final decision on CBI’s motion to dismiss. We believe Mr. Chien’s claims to be meritless and will continue to contest them vigorously.

Corporate History

We were founded under the name “Commonwealth Biotechnologies, Inc.” in Virginia in 1992, and completed an initial public offering in October 1997 (we refer to our company prior to our emergence from bankruptcy as CBI). CBI previously provided, on a contract basis, specialized life sciences services to the pharmaceutical and biotechnology sector through Mimotopes Pty Limited, a wholly-owned subsidiary of CBI. On January 20, 2011, CBI filed a voluntary petition captioned *In re Commonwealth Biotechnologies, Inc., Case No. 11-30381-KRH* in the United States Bankruptcy Court for the Eastern District of Virginia seeking relief under the provisions of Chapter 11 of Title 11 of the United States Code. On April 7, 2011, the bankruptcy court approved the private sale of the Mimotopes business unit for a net sales price of $850,000. The sale closed on April 29, 2011.

On January 4, 2013, CBI filed an Amended Plan of Reorganization (which we refer to as the Plan) with the bankruptcy court. The Plan was approved by a vote of creditors and CBI stockholders on March 21, 2013. Under the Plan, all debts of CBI were terminated and all outstanding options and warrants were cancelled. In addition, CBI received an auction fee of $30,000 from Hedgepath, LLC, a Florida limited liability company controlled by our current Executive Chairman, Dr. Frank E. O’Donnell, Jr., and Hedgepath, LLC agreed to contribute to our company certain assets related to our current cancer therapy business. Hedgepath, LLC was the winning bidder for CBI in the bankruptcy case.

On March 29, 2013, the bankruptcy court entered a confirmation order confirming the Plan pursuant to Chapter 11 of the Bankruptcy Code. Under the terms of the Plan, and pursuant to a Contribution Agreement between Hedgepath, LLC and our company, Hedgepath, LLC contributed and assigned certain assets and rights to us, as the reorganized debtor, in exchange for the right to receive 90% of fully diluted voting equity in our company on the date of issuance (in the form of shares of our Series A Preferred Stock, which were subsequently converted to shares of common stock), with the prior stockholders of CBI retaining approximately 10% voting equity in our company at that time. The contributed assets consisted of:

(i) U.S. Provisional Patent Application 61-831,122, "Prostate-Specific Antigen as Biomarker for Hedgehog Pathway Inhibitor Treatment and Prognostic Monitoring of Prostate Cancer" (previously assigned to Hedgepath, LLC by Dr. Frank E. O'Donnell, Jr. and Nicholas J. Virca, as inventors);

(ii) U.S. Provisional Patent Application 61-813,823, "Treatment and Prognostic Monitoring of Cancer Using Hedgehog Pathway Inhibitors" (previously assigned to Hedgepath, LLC by Dr. Frank E. O'Donnell, Jr. and Nicholas J. Virca, as inventors);

(iii) Assignment of Patents, dated November 1, 2012, by Dr. Frank E. O'Donnell, Jr. in favor of Hedgepath, LLC;

(iv) Assignment of Patents, dated November 1, 2012, by Nicholas J. Virca in favor of Hedgepath, LLC;

(v) Consulting Agreement, dated and effective as of September 1, 2012, by and between HPPI (as successor to Hedgepath, LLC) and Emmanuel Antonarakis, MD;

(vi) Confidentiality and Intellectual Property Assignment Agreement, dated and effective September 1, 2012, between Dr. Antonarakis and our company (as successor to Hedgepath, LLC), which includes all intellectual property, know-how and other assets assigned to Hedgepath, LLC by Dr. Antonarakis under such agreement;

(vii) Consulting Agreement, effective as of April 11, 2013, by and between Hedgepath, LLC and Arianne Consulting, Inc.; and

(viii) Confidentiality and Intellectual Property Assignment Agreement, dated and effective April 11, 2013, between Arianne Consulting and Hedgepath, LLC , which includes all intellectual property, know-how and other assets assigned to Hedgepath, LLC by Arianne Consulting under such agreement.

On August 12, 2013, in furtherance of CBI's emergence from bankruptcy, CBI effected a "short-form" reincorporation merger with HedgePath Pharmaceuticals, Inc., a newly created and wholly-owned Delaware subsidiary of CBI, pursuant to which CBI merged with and into our company, with our company surviving the merger and with the effect of CBI becoming reincorporated as a Delaware corporation and changing its corporate name to HedgePath Pharmaceuticals, Inc.

Employees

As of June 30, 2014, we have 2 full-time employees who have entered into multi-year employment agreements with us and 2 part-time employees. One is involved in our clinical development program and operations and three handle our administration and accounting. None of our employees are covered by collective bargaining agreements. From time to time, we also employ independent contractors to support our clinical development and administrative functions. We consider relations with all of our employees to be good. Each of our employees has also entered into confidentiality, intellectual property assignment and non-competition agreements with us.

Facilities

Hedgepath, LLC has allocated space for our use in its offices in Tampa, Florida and San Diego, California, for which we currently do not pay rent.

MANAGEMENT

Set forth below is information regarding our current directors and executive officers. Each director holds his office until he resigns or is removed and his successor is elected and qualified.

Name	Age	Position
Frank E. O'Donnell, Jr., M.D.	64	Executive Chairman and Director
Nicholas J. Virca	67	President and Chief Executive Officer
Garrison J. Hasara, CPA	44	Chief Financial Officer and Treasurer
Samuel P. Sears, Jr.	70	Director
W. Mark Watson, CPA	64	Director
Stefan J. Cross	41	Director
Dr. R. Dana Ono	61	Director

Mayne Pharma has the right to designate one director to our Board of Directors and to designate a second director if the size of the Board is increased to seven directors until the earlier to occur of: (i) the date that the Amended and Restated Supply and License Agreement is terminated or expires or (ii) the date on which Mayne Pharma ceases to own ten percent (10%) or more of our issued and outstanding common stock on a fully diluted basis. Mayne Pharma's current designee to our Board of Directors is Stefan J. Cross.

There are no family relationships between any of our directors or executive officers.

Frank E. O'Donnell, Jr., M.D., age 64, is our Executive Chairman of the Board and a Director of our company. He has been the Chairman of the Board of BioDelivery Sciences International (NASDAQ:BDSI) since 2002, and currently serves as Executive Chairman of BDSI. For more than six years, Dr. O'Donnell has been involved with various private limited liability companies which engage in private equity and venture capital investing in disruptive technologies in healthcare, including Hedgepath, LLC. Dr. O'Donnell is qualified to serve on our Board of Directors due to his medical training and extensive experience with investing in and operating biotechnology companies. Dr. O'Donnell is a graduate of The Johns Hopkins School of Medicine and received his residency training at the Wilmer Ophthalmological Institute, Johns Hopkins Hospital. Dr. O'Donnell is a former professor and Chairman of the Department of Ophthalmology, St. Louis University School of Medicine. He is a trustee of St. Louis University.

Nicholas J. Virca, age 67, has been our President and Chief Executive Officer since August 2013 and has been working on our business opportunity with Hedgepath, LLC since April 2012. From 2008 until April 2012, Mr. Virca served as the Chief Operating Officer for LamdaGen Corporation, a privately held company focused on monitoring assays for biopharmaceutical development and manufacturing applications, as well as high-sensitivity detection for human diagnostic biomarkers, such as oncoproteins related to cervical cancer. From 2005 to 2008, Mr. Virca was Vice President for Global Biotechnology at Pall Life Sciences where he was responsible for growth strategies and programs in the biotechnology arena, including new technology and product initiatives, joint ventures, licensing and acquisitions. He also founded the first Scientific Advisory Board for Pall's Biopharmaceuticals Division. From 1997 to 2004, Mr. Virca was COO, and later CEO and President of Adventrx Pharmaceuticals focusing on anti-cancer drug development in human clinical trials. He was instrumental in transitioning the company from a private corporation to a listing on the American Stock Exchange. Mr. Virca held various marketing and general management positions at Damon Biotech, Promega Corporation, Nicolet Imaging Systems, Ortho Diagnostic Systems, Fisher Scientific, Waters, Ross Laboratories and Pfizer Diagnostics. Mr. Virca currently serves on the board of Panoptix Events and on the Life Sciences Advisory Board of Entegris, Inc. He previously served on the boards of Adventrx Pharmaceuticals between 2001 and 2004, and Diametrix Detectors between 1991 and 1997. He earned a bachelor's degree in Biology from Youngstown State University, is the co-inventor of packaging technology for enzyme research reagents, and is a member of numerous biotechnology organizations for which he has been a speaker and organizer over the last two decades.

Garrison J. Hasara, CPA, age 44, has been our Chief Financial Officer and Treasurer since September 2013. From January 2011 to September 2013, he was the Acting Chief Financial Officer, Principal Financial Officer and Principal Accounting Officer of Accentia Biopharmaceuticals, Inc., a biotechnology company focused on discovering, developing and commercializing innovative therapies that address the unmet medical needs of patients by utilizing therapeutic clinical products. He also served as Accentia's Controller, a position that he held since June 2005. From November 2003 to June 2005, Mr. Hasara served as Accentia's Compliance Specialist. Prior to that time, from 2000 to 2003, Mr. Hasara was the Chief Financial Officer of Automotive Service Centers, Inc., a franchisee of Midas, Inc. In addition, from 1996 to 1999, Mr. Hasara served in various accounting roles at KForce Inc., a publicly traded staffing services company. Mr. Hasara has been a licensed Certified Public Accountant since 1993 and received his B.S. from the University of South Florida in 1991.

Samuel P. Sears, Jr., age 70, is a director of our company. He has been a member of the Board of Directors of BioDelivery Sciences International since October 2011 (NASDAQ: BDSI). Mr. Sears has extensive experience in the biopharmaceutical, nutraceutical and biotechnology industries. Since 2006, Mr. Sears has been a partner at the law firm of Cetrulo LLP, where he currently serves as managing partner, and from 2000 to 2006, he provided private consulting and legal advisory services to start-up and early stage development companies. From 2000 to 2013, Mr. Sears served as Director, Chairman of the Audit Committee, Chairman of the Executive Committee, and Member of the Compensation Committee of Commonwealth Biotechnologies, Inc., a research and development support services company. From 1998 to 2000, Mr. Sears served as Vice Chairman and Treasurer of American Prescription Providers, Inc., a specialty pharmacy network offering prescriptions and nutraceuticals to patients with chronic diseases. From 1994 through May 1998, Mr. Sears was Chief Executive Officer and Chairman of Star Scientific, Inc. From 1968 to 1993, Mr. Sears was in private law practice. Mr. Sears is qualified to serve on our Board of Directors because of his extensive legal and business experience, including in the pharmaceutical industry. Mr. Sears is a graduate of Harvard College and Boston College Law School.

W. Mark Watson, CPA, age 64, is a director of our company. Mr. Watson is a Certified Public Accountant with over 40 years of experience in public accounting and auditing, having spent his entire career from January 1973 to June 2013at Deloitte Touche Tohmatsu and its predecessor, most recently as Central Florida Marketplace Leader. Among other industries, he has a particular expertise in the health and life sciences sector, having played a significant role in the development of Deloitte's audit approach for health and life sciences companies and leading its national healthcare regulatory and compliance practice. He has served as lead audit partner and advisory partner on the accounts of many public companies ranging from middle market firms to Fortune 500 enterprises. Mr. Watson is a member of American Institute of Certified Public Accountants, the Florida Institute of Certified Public Accountants and the New York State Society of Public Accountants. Mr. Watson is qualified to serve on our Board of Directors due to his expertise in public accounting and his experience with pharmaceutical companies. He received his undergraduate degree in Accounting from Marquette University.

Stefan J. Cross, age 41, is a director of our company and the appointee of Mayne Pharama to our Board of Directors. Since November 2013, Mr. Cross has served as the President of the U.S. subsidiaries of Mayne Pharma Group Limited (ASX: MYX). Mr. Cross has more than 20 years of experience in the pharmaceutical industry. Prior to his current appointment as President, he served since 2012 as the Vice President, Business and Corporate Development of Mayne Pharma's non-U.S. operations, where he was responsible for all in-licensing and out-licensing programs and research and development partnerships. Prior to joining Mayne Pharma, Mr. Cross was, from 2007 to 2012, Head of Marketing (Asia Pacific) for Hospira Inc., a leading global provider of pharmaceuticals and medical devices, where he was responsible for expansion of the new product portfolio and on-market product growth across all markets in the region. Prior to Hospira, Mr. Cross spent most of the period from 1991 to 2007 working in the pharmaceutical sector in the areas of strategy, business development/mergers and acquisitions, sales and marketing, human resources, finance and information technology. Mr. Cross is qualified to serve on our Board of Directors because of his extensive business experience in the pharmaceutical industry. Mr. Cross holds a Masters in Business in Administration from Swinburne University of Technology, Australia, and a degree in Business Information Systems from the University of South Australia.

Dr. R. Dana Ono, age 61, is a director of our company. Dr. Ono is a co-founder of, and since 2000 has been associated with, the VIMAC Milestone Medica Fund LP, a Boston-based early-stage life sciences fund co-sponsored by VIMAC Ventures LLC and RBC Technology Ventures, Inc. Dr. Ono has 30 years of experience in managing public and private life science companies, including, from 1995 to 2000, serving as President and Chief Executive Officer of IntraImmune Therapies, Inc., which was sold to Abgenix, Inc. in 2000. Throughout his career, he has been engaged in the strategic planning, product management, technology acquisition, and commercial development of life science start-ups and has been involved in a number of pioneering milestones in biotechnology. He has founded several biotech companies in the U.S., including in the areas of drug discovery and development, nutraceuticals and cosmeceuticals. He is a founding director of the Massachusetts Biotechnology Council, Inc. and serves on the Board of Trustees of the Marine Biological Laboratory in Woods Hole, Massachusetts. Dr. Ono is qualified to serve on our Board of Directors because of his medical and business expertise, particularly in the pharmaceutical industry. Dr. Ono received his AB in Earth & Planetary Sciences from The Johns Hopkins University and his AM and PhD in Biology from Harvard University, where he also completed a program in business administration.

Key Employee

Below is the biography of a key employee of our company who, although not a named executive officer, we consider important to our business.

James A. McNulty, *CPA*, age 63, is our Secretary and Compliance Officer. From 2000 through October 2013, Mr. McNulty served as Chief Financial Officer of BioDelivery Sciences International, Inc. (NASDAQ: BDSI) and currently serves as that company's Senior Vice President - Finance and Treasurer . Mr. McNulty also serves as Chief Financial Officer for Hopkins Capital Group, an affiliation of limited liability companies which engage in venture investing activities. He was the Chief Financial Officer of Star Scientific, Inc. from 1998 to- 2000 and from 2000 to 2002 he was the CFO/COO of American Prescription Providers, Inc. Mr. McNulty has performed accounting and consulting services as a Certified Public Accountant since 1975. He co-founded Pender McNulty & Newkirk, and was a founder/principal in two other CPA firms, McNulty & Company, and McNulty Garcia & Ortiz. He is a Director of Quantum Technology Sciences, Inc., a private company. He is a published co-author (with Pat Summerall) of Business Golf, the Art of Building Relationships on the Links. Mr. McNulty is a graduate of University of South Florida, a licensed Certified Public Accountant, a member of the American and Florida Institutes of CPA's and is a board member of the Tampa Bay chapter of Financial Executives International.

Certain Legal Proceedings

Our Executive Chairman, Frank E. O'Donnell, Jr., M.D., and our Chief Financial Officer and Treasurer, Garrison J. Hasara, previously served as the Executive Chairman and Controller, respectively, of Accentia Biopharmaceuticals, Inc. (which we refer to as Accentia). In 2008, Accentia and its then majority owned subsidiary Biovest International, Inc. (which we refer to as Biovest and of which Dr. O'Donnell also served as Executive Chairman) filed for Chapter 11 bankruptcy protection, from which they emerged in 2010. In March 2013, Biovest again filed for Chapter 11 bankruptcy protection, from which it emerged in July 2013. Under Biovest's 2013 plan of reorganization, Accentia's equity ownership in Biovest was cancelled.

Board Committees and Director Independence

Director Independence

Of our current directors, we have determined that Samuel P. Sears, Jr., Dr. R. Dana Ono, and W. Mark Watson are "independent" as defined by NASDAQ Stock Market rules. Accordingly, a majority of our Board of Directors is "independent."

Board Committees

Our Board of Directors has established three standing committees — Audit, Compensation, and Nominating and Corporate Governance. All standing committees operate under a charter that has been approved by our Board of Directors.

Audit Committee

Our board of directors has an Audit Committee, composed of W. Mark Watson, Stefan J. Cross and Samuel P. Sears, Jr. Mr. Watson and Mr. Sears are independent directors as defined in accordance with Rule 10A-3 of the Securities Exchange Act of 1934, as amended, and the rules of the NASDAQ Stock Market. Mr. Watson serves as chairman of the committee. The board of directors has determined that Mr. Watson is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K.

Our Audit Committee oversees our corporate accounting, financial reporting practices and the audits of financial statements. For this purpose, the Audit Committee has a charter (which will be reviewed annually) and performs several functions. The Audit Committee:

- evaluates the independence and performance of, and assesses the qualifications of, our independent auditor and engages such independent auditor;
- approves the plan and fees for the annual audit, quarterly reviews, tax and other audit-related services and approves in advance any non-audit service and fees therefor to be provided by the independent auditor;
- monitors the independence of the independent auditor and the rotation of partners of the independent auditor on our engagement team as required by law;
- reviews the financial statements to be included in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and reviews with management and the independent auditors the results of the annual audit and reviews of our quarterly financial statements;
- oversees all aspects of our systems of internal accounting and financial reporting control and corporate governance functions on behalf of the board; and

- provides oversight assistance in connection with legal, ethical and risk management compliance programs established by management and the board, including compliance with requirements of Sarbanes-Oxley and makes recommendations to the board of directors regarding corporate governance issues and policy decisions.

Nominating and Corporate Governance Committee

Our board of directors has a Nominating and Corporate Governance Committee composed of Dr. R. Dana Ono, Stefan Cross and W. Mark Watson. Dr. Ono serves as the chairman of the committee. The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing our corporate governance policies and with proposing potential director nominees to the board of directors for consideration. The Nominating and Corporate Governance Committee has a charter which is reviewed annually. Dr. Ono and Mr. Watson are independent directors in accordance with the rules of the NASDAQ Stock Market. The Nominating and Corporate Governance Committee will consider director nominees recommended by security holders.

Compensation Committee

Our board of directors also has a Compensation Committee, which reviews or recommends the compensation arrangements for our management and employees and also assists the board of directors in reviewing and approving matters such as company benefit and insurance plans, including monitoring the performance thereof. The Compensation Committee has a charter (which will be reviewed annually) and is composed of three members: Samuel P. Sears, Jr., Stefan Cross and Dr. R. Dana Ono. Mr. Sears serves as chairman of this committee. Mr. Sears and Dr. Ono are independent in accordance with rules of the NASDAQ Stock Market.

Code of Business Conduct and Ethics and Insider Trading Policy

In July 2014, our Board of Directors adopted a Code of Ethical Conduct and an Insider Trading Policy.

Executive Compensation

The following table sets forth all compensation paid to our named executive officers at the end of the fiscal years ended December 31, 2013 and 2012. Individuals we refer to as our "named executive officers" include our Chief Executive Officer and our most highly compensated executive officers whose salary and bonus for services rendered in all capacities exceeded $100,000 during the fiscal year ended December 31, 2013.

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compen-sation ($)	Nonqualified Deferred Compen-sation Earnings ($)	All Other Compen-sation ($)	Total ($)
Nicholas J. Virca President, Chief Executive Officer and Director(1)	2013	$120,000	—	—	—	—	—	—	$120,000
	2012	—	—	—	—	—	—	—	—
Garrison J. Hasara Chief Financial Officer and Treasurer(2)	2013	$ 72,692	—	—	—	—	—	$ 3,890(3)	$ 76,582
	2012	—	—	—	—	—	—	—	—
Richard J. Freer,Ph.D. Former Chief Executive Officer(4)	2013	$186,296(5)	—	—	—	—	—	$ 29,912(6)	$216,208
	2012	$ 18,984	—	—	—	—	—	$ 44,325(7)	$ 63,309

(1) Nicholas J. Virca was hired as Chief Executive Officer on August 1, 2013
(2) Garrison J. Hasara was hired as Chief Financial Officer on August 1, 2013
(3) Includes: $3,890 of health insurance premiums paid in 2013.
(4) Richard J. Freer served as Chief Executive Officer until August 1, 2013
(5) The compensation disclosed in this item is composed of accrued 2012 and 2011 compensation, as paid in 2013.
(6) Includes: $28,100 in consulting services and $1,812 of health insurance premiums paid in 2013.
(7) Includes: $44,325 in consulting services paid in 2012.

Outstanding equity awards

There were no outstanding unexercised options, unvested options or shares and equity incentive plan awards held by each of our named executive officers, as of December 31, 2013. All of CBI's equity incentive plans and awards were canceled on July 16, 2013, which was 90 days subsequent to the effective date of the emergence from bankruptcy.

In July 2014, our Board of Directors granted an aggregate of 23,541,738 restricted stock units under our 2014 Equity Incentive Plan, which plan is described below. Of this amount, Nicholas J. Virca and Garrison J. Hasara received 15,041,738 and 7,000,000 restricted stock units, respectively

2014 Equity Incentive Plan

In July 2014, our Board of Directors adopted our 2014 Equity Incentive Plan (which we refer to the EIP), subject to approval by a majority of the holders of our common stock. The EIP is comprised of approximately 32,583,475 shares of our common stock (ranking paripassu with our issued and outstanding common stock) to be available in the form of incentive stock options, non-qualified stock options, restricted stock, restricted stock units, performance awards and other customary equity incentives.

The purpose of our EIP is to attract and retain directors, officers, consultants, advisors and employees whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in our development and financial achievements. The EIP will be administered by the compensation committee of our Board of Directors or by the full Board of Directors, which may determine, among other things, (a) the persons who are to receive awards, (b) the type or types of awards to be granted to such persons, (c) the number of shares of common stock to be covered by, or with respect to which payments, rights, or other matters are to be calculated in connection with the awards, (d) the terms and conditions of any awards, (e) whether, to what extent, and under what circumstances awards may be settled or exercised in cash, shares of common stock, other securities, other awards or other property, or canceled, forfeited, or suspended and the method or methods by which awards may be settled, exercised, canceled, forfeited, or suspended, (f) whether, to what extent, and under what circumstances the delivery of cash, shares of common stock, other securities, other awards or other property and other amounts payable with respect to an award, (g) interpret, administer, reconcile any inconsistency in, settle any controversy regarding, correct any defect in and/or complete any omission in the EIP and any instrument or agreement relating to, or award granted under, the EIP, (h) establish, amend, suspend, or waive any rules and regulations and appoint such agents as the compensation committee deems appropriate for the proper administration of the EIP, (i) accelerate the vesting or exercisability of, payment for or lapse of restrictions on, awards and (j) make any other determination and take any other action that the compensation committee deems necessary or desirable for the administration of the EIP.

The EIP provides that in the event of a change of control event, (i) all of the then outstanding options and stock appreciation rights granted pursuant to the EIP will immediately vest and become immediately exercisable as of a time prior to the change in control, (ii) any performance goal restrictions related to an award will expire as of a time prior to the change in control and (iii) any performance periods that relating to an award which have not yet expired on the date the change in control occurs will end on such date, and the compensation committee will (a) determine the extent to which performance goals with respect to each such performance period have been met based upon such audited or unaudited financial information or other information then available as it deems relevant and (b) cause the relevant participant to receive partial or full payment of awards for each such performance period based upon the compensation committee's determination of the degree of attainment of the performance goals, or assuming that the applicable "target" levels of performance have been attained or on such other basis determined by the compensation committee.

In addition, subject to our Equity Holders Agreement, our Board of Directors may amend our EIP at any time. However, without stockholder approval, our EIP may not be amended in a manner that would:

- increase the number of shares that may be issued under our EIP;
- materially modify the requirements for eligibility for participation in our EIP;
- materially increase the benefits to participants provided by our EIP; or
- otherwise disqualify our EIP for coverage under Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended.

Awards previously granted under our EIP may not be impaired or affected by any amendment of our EIP, without the consent of the affected grantees.

Option Exercises and Stock Vested

There were no options exercised by the executive officers during the year ended December 31, 2013.

Compensation of Directors

There was no compensation to directors during the year ended December 31, 2013. In July 2014, each of our directors other than Dr. O'Donnell were awarded 300,000 restricted stock units under our 2014 Equity Incentive Plan. In addition, we plan on establishing a non-employee director remuneration policy, which may consist of customary cash and equity awards.

Employment Agreements

On June 24, 2014, Nicholas J. Virca, our President and Chief Executive Officer, entered into an employment agreement with us. Pursuant to his employment agreement, Mr. Virca will act as our President and Chief Executive Officer for a term of three (3) years from the effective date of the agreement. At the end of the three year term, the agreement will automatically renew for successive one year terms unless prior written notice is received from either party within 60 days prior to the end of the particular term. Mr. Virca will earn a base salary of $150,000 per year for services rendered. Such base salary will automatically increase to $250,000 per year upon achievement of certain funding goals as described in the employment agreement. Mr. Virca is also eligible for a bonus in cash or in kind of up to 50% of his base salary based upon his achievement of certain goals as established by the Board of Directors or a committee of the Board of Directors. In addition, in July 2014, Mr. Virca was awarded 15,041,738 restricted stock units from the EIP, subject to approval by our majority stockholders. Such restricted stock units will vest on the earlier to occur of September 3, 2016 and the receipt of written notice of acceptance for the filing of an NDA by us for SUBA-Itraconazole by the relevant regulatory authority.

Mr. Virca's employment agreement may be terminated with or without cause by us or for or without good reason by Mr. Virca. In the event that the employment agreement is terminated for cause by us or without good reason by Mr. Virca, Mr. Virca is entitled to receive all accrued but unpaid salary and bonus amounts. In the event that the employment agreement is terminated without cause by us or for good reason by Mr. Virca, Mr. Virca is entitled to all accrued but unpaid salary and bonus amounts plus a cash payment equal to six months of Mr. Virca's base salary, provided that such payment will equal twelve months of Mr. Virca's base salary if we have reached certain milestones. In the event that the employment agreement is terminated for good reason by Mr. Virca following a change of control, Mr. Virca is entitled to all accrued but unpaid salary and bonus amounts plus a cash payment equal to twelve months of Mr. Virca's base salary, provided that such payment will equal eighteen months of Mr. Virca's base salary if we have reached certain performance milestones. The employment agreement is also terminable upon death and disability and upon the terms as described in the Equity Holders Agreement between Hedgepath, LLC and Mayne Pharma described under "Certain Relationships and Related Party Transactions. Mr. Virca may not compete against us or solicit employees or customers from us for a period of one (1) year after termination of his employment for any reason as described in his employment agreement.

On June 24, 2014, we and Frank E. O'Donnell, Jr., M.D., our Executive Chairman, entered into an Executive Chairman Agreement to memorialize the terms under which Dr. O'Donnell will continue to serve in such capacity and as a director of our company. The Executive Chairman Agreement will continue until the date that Dr. O'Donnell is no longer serving as a member of our Board of Directors. For services rendered as Executive Chairman, Dr. O'Donnell is entitled to cash compensation of $43,200 per year, increasing to $72,000 per year upon achievement of the certain funding goals. Dr. O'Donnell is further entitled to an annual bonus in cash or in securities of our company of up to 50% of Dr. O'Donnell's annual fee. Dr. O'Donnell may not compete against us or solicit employees or customers from us for a period of one year after termination of the Executive Chairman Agreement as described in further detail in the same. The Executive Chairman Agreement may be terminated by either us or Dr. O'Donnell with 60 days' written notice and upon the terms as described above in the Equity Holders Agreement. Upon termination, we will be required to pay Dr. O'Donnell all compensation and expenses that are owed to him as of the date of termination.

On September 4, 2014, we and Garrison Hasara, our Chief Financial Officer and Treasurer, entered into an employment agreement to memorialize the terms under which Mr. Hasara will continue to serve in such capacity. The employment agreement has a term through December 31, 2017. For services rendered, Mr. Hasara is entitled to cash compensation of $135,000 per year, increasing to $180,000 per year upon closing on a follow-on public offering. Mr. Hasara is further entitled to an annual bonus in cash or in securities of our company of up to 50% of Mr. Hasara's annual fee beginning with fiscal year 2015. In addition, Mr. Hasara was awarded 7,000,000 restricted stock units from the EIP, subject to approval by our majority stockholders. Such restricted stock units will vest on the earlier to occur of September 3, 2016 and the receipt of written notice of acceptance for the filing of an NDA by us for SUBA-Itraconazole by the relevant regulatory authority.

Mr. Hasara's employment agreement may be terminated with or without cause by us or for or without good reason by Mr. Hasara. In the event that the employment agreement is terminated for cause by us or without good reason by Mr. Hasara, Mr. Hasara is entitled to receive all accrued but unpaid salary and bonus amounts. In the event that the employment agreement is terminated without cause by us or for good reason by Mr. Hasara, Mr. Hasara is entitled to all accrued but unpaid salary and bonus amounts plus a cash payment equal to six months of Mr. Hasara's base salary, provided that such payment will equal twelve months of Mr. Hasara's base salary if we have reached certain milestones. In the event that the employment agreement is terminated for good reason by Mr. Hasara following a change of control, Mr. Hasara is entitled to all accrued but unpaid salary and bonus amounts plus a cash payment equal to twelve months of Mr. Hasara's base salary. The employment agreement is also terminable upon death and disability. Mr. Hasara may not compete against us or solicit employees or customers from us for a period of one (1) year after termination of his employment for any reason as described in his employment agreement.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Hedgepath, LLC

August 2013 Contribution Agreement

As part of our bankruptcy reorganization plan, on August 13, 2013, we entered into the Contribution Agreement with Hedgepath, LLC, one of our principal stockholders, pursuant to which we acquired certain assets related to the our current business, and Hedgepath, LLC was issued the Series A Preferred Stock representing a 90% equity voting interest in our company. Hedgepath, LLC is a private company. Blackrobe Capital LLC, an entity managed by our executive chairman, Dr. O'Donnell, is also the manager of Hedgepath, LLC. Effectively, Dr. O'Donnell controls Hedgepath, LLC.

June 2014 Purchase Agreement

On the June 24, 2014 as a condition to the Mayne Purchase Agreement (as defined and described below), we entered into a Stock Purchase Agreement with Hedgepath, LLC. Pursuant to such agreement, Hedgepath, LLC purchased 20,000,000 shares of our common stock at a purchase price of $0.075 per share for an aggregate purchase price of $1,500,000. Such purchase price is payable as follows: (i) an advance payment of $125,000 made by Hedgepath, LLC on June 4, 2014 was deemed partial funding of the purchase price; (ii) a payment of $125,000 was made by Hedgepath, LLC on June 24, 2014; and (iii) the remaining $1,250,000 will be funded in monthly installments through December 31, 2014 pursuant to a promissory note issued by Hedgepath, LLC to us. Pursuant to the note, commencing on June 30, 2014 and ending on December 31, 2014, Hedgepath, LLC must make monthly payments to us in accordance with the terms and conditions of the note. We have the right, in our sole discretion, to request an advance payment of part or all of the principal of the note. The note bears no interest except upon an event of default in which case interest accrues at 18% per annum. In the event that Hedgepath, LLC defaults on part or all of the note, we have the right to declare by written notice that Hedgepath, LLC forfeit some or all of the 20,000,000 shares of common stock purchased as well as 17,646.98 shares of Series A Preferred Stock (or the common stock equivalent upon conversion thereof) held by Hedgepath, LLC as described further below.

Debt Forgiveness Agreement

On June 24, 2014, as a condition of closing of the Mayne Purchase Agreement, we entered into a Debt Forgiveness Agreement with Hedgepath, LLC pursuant to which Hedgepath, LLC waived, canceled and forgave payment from us of an aggregate of $639,767 of indebtedness previously advanced by Hedgepath, LLC to us in exchange for 2,530,227 shares of common stock, 71,635.981 shares of Series A Preferred Stock and a warrant to purchase 10,250,569 shares of common stock. The shares of Series A Preferred Stock converted into 82,156,842 shares of common stock on August 14, 2014. The warrant may be exercised by Hedgepath, LLC at an exercise price of $0.0878 per share at any time, from time to time, by Hedgepath, LLC prior to expiration on June 24, 2019.

Equity Holders Agreement

On June 24, 2014, in fulfillment of one of the conditions of the Mayne Purchase Agreement, we, Mayne Pharma, Hedgepath, LLC, Dr. O'Donnell and Mr. Virca (who for these purposes we refer to together as the Equity Holder Parties) entered into an Equity Holders Agreement (which we refer to as the Equity Holders Agreement). The Equity Holders Agreement governs the rights and obligations of each of the parties as they pertain to our securities and to the present and future governance of our company. Pursuant to the Equity Holders Agreement:

- Mayne Pharma and Hedgepath, LLC each agreed not to offer, pledge, sell, contract to sell, swap or enter into any other transfer arrangement any of their Company securities until June 24, 2015 (which we refer to as the Lock-Up Period) without prior written consent of the other Equity Holder Parties, except for in limited circumstances as described in the Equity Holders Agreement;
- Mayne Pharma, Hedgepath, LLC, Mr. Virca and Dr. O'Donnell each agreed that during the Lock-Up Period none of them will own greater than 49.5% of our common stock on a fully-diluted basis (such ownership to include individual and affiliate ownership) and that after the Lock-Up Period and until August 14, 2019, each of the Equity Holder Parties will provide written notice to each of the other Equity Holder Parties if their ownership (together with affiliates) exceeds, or is going to exceed, 49.5%;

- Mayne Pharma and its affiliates have been granted a right of first refusal to purchase a pro rata share of any new securities issued by us, such pro rata share to be determined based upon the number of shares of common stock held by Mayne Pharma on a fully diluted basis as compared to the number of shares of common stock outstanding immediately prior to the offering of the new securities on a fully diluted basis;
- Mayne Pharma has been granted the right until June 24, 2016 to introduce accredited investors to us to participate in a private offering of our securities (with some exceptions as described in the Equity Holders Agreement). In the event that we contemplate a private offering of our securities, such accredited investors introduced by Mayne Pharma to have the right to participate in up to 50% of the private offering;
- Mr. Virca agreed to lock-up his equity securities of our company until the earlier of: (i) September 3, 2016, (ii) the receipt of written notice of acceptance for the filing of an NDA for the product licensed to us by Mayne Pharma, or, (iii) to the extent provided in an applicable award agreement, upon his death or disability;
- Dr. O'Donnell and we agreed that Dr. O'Donnell is not entitled to receive any equity securities under our EIP until June 24, 2015;
- we agreed not to amend the EIP in any way during the Lock-Up Period without written consent of Mayne Pharma;
- The Equity Holder Parties agreed that all awards included in the initial issuance of securities from the EIP are subject to restriction on exercise until the earlier of: (i) September 3, 2016 and (ii) the receipt of written notice of acceptance for the filing of an NDA by us an NDA for the product licensed to us by Mayne Pharma, provided that any awards granted after June 24, 2014 are not subject to this restriction;
- Mayne Pharma has the right to designate one director to the our Board of Directors and to designate a second director if the size of the board is increased to seven directors until the earlier to occur of: (i) the date that the Amended and Restated Supply and License Agreement is terminated or expires, or (ii) the date on which the Mayne Pharma or its affiliates ceases to own ten percent (10%) or more of the issued and outstanding common stock on a fully diluted basis (which we call the Voting Rights Termination Date);
- The Equity Holder Parties agree that, for as long as Mayne Pharma has the right to designate a director to our Board of Directors, all of the Equity Holder Parties will vote their shares in favor of appointing the Mayne Pharma candidate to the board;
- The Equity Holder Parties agree not to increase or decrease the size of our Board of Directors except with the unanimous consent of the board until the Voting Rights Termination Date;
- Until the Voting Rights Termination Date, the Equity Holder Parties agree that any replacement or removal of Mr. Virca requires the unanimous approval of the Board of Directors;
- Until the Voting Rights Termination Date, the Equity Holder Parties agree that any replacement or removal of Dr. O'Donnell requires the approval of all of the members of the Board of Directors except for Dr. O'Donnell;
- The Equity Holder Parties agree that the terms of our promissory note with Hedgepath, LLC cannot be amended without unanimous approval of all disinterested directors;

- Mayne Pharma was granted a right of first refusal to purchase any shares of our common stock being transferred or sold by the individual account of Dr. O'Donnell or Mr. Virca except for certain exempt transfers as described in the Equity Holders Agreement;
- The Equity Holder Parties agreed that if Hedgepath, LLC defaults under its promissory note with us, or breaches any provisions of such note, then we have the right to declare that approximately 6 million shares of common stock be forfeited and Mayne Pharma has the right to purchase such forfeited shares; and
- The Equity Holder Parties agreed that if Hedgepath, LLC defaults under the its promissory note or breaches any provisions of such note, then Mayne Pharma has the right to demand the resignation of Dr. O'Donnell.

In addition to the foregoing, the Equity Holder Parties also agreed that we would seek to meet certain goals for the commercialization of our product and certain funding goals for our company. In the event that we fail to achieve such goals, Mayne Pharma has the right to demand the resignation of Dr. O'Donnell and/or Mr. Virca from their positions with our company. In the event that Dr. O'Donnell or Mr. Virca do not submit their resignations in a timely manner, Mayne Pharma can terminate the Amended and Restated Supply and License Agreement. Additionally, if the commercialization goals are not achieved, we have the right to declare that Hedgepath, LLC forfeit approximately 6 million shares of common stock.

If Dr. O'Donnell or Mr. Virca are required to resign pursuant to the Equity Holders Agreement, then, notwithstanding employment agreements with us, no severance, compensation, consideration or other payment will be due or payable in connection therewith and they will forfeit all then unvested options, warrants, restricted stock units, or other right to acquire shares of our common stock (or securities convertible into common stock) and will waive any claim to severance pay. Furthermore, upon such resignation or termination, Mayne Pharma will have the right to purchase by written notice to Dr. O'Donnell or Mr. Virca, as the case may be, all company securities owned by them, including vested options, vested warrants, vested restricted stock units and the like individually held by them or otherwise transferred by either of them, as the case may be, at the fair market value (as such term is defined in the Equity Holders Agreement) as of the date of such resignation or termination.

The Equity Holders Agreement terminates (i) if we receive an adjudication of bankruptcy, we execute an assignment for the benefit of creditors, a receiver is appointed for us or we are voluntarily or involuntarily dissolved or (ii) if we, Hedgepath, LLC and Mayne Pharma expressly agree in writing. Additionally, certain limited provisions of the Equity Holders Agreement terminate at such time as the Mayne Pharma and its affiliates collectively own less than ten percent (10%) of our common stock on a fully diluted basis.

Mayne Pharma

Amended and Restated License and Supply Agreement

Pursuant to our Supply and License Agreement with Mayne Pharma, which was originally entered into on September 3, 2013 and most recently amended and restated on June 24, 2014, Mayne Pharma is obligated to: (i) supply us with its patented formulation of SUBA-Itraconazole in a particular dose formulation for the treatment of human patients with cancer via oral administration (with the initial areas of investigation being prostate, lung and skin cancer) in the United States, (ii) provide us with an exclusive license to perform specified development activities and to commercialize SUBA-Itraconazole for the treatment of cancer via oral administration in the United States and (iii) participate in a joint development committee (or JDC) with us to clinically develop SUBA-Itraconazole for the treatment of cancer in the United States. The Supply and License Agreement may be terminated by Mayne Pharma if we fail to achieve regulatory approval to commercialize SUBA-Itraconazole in the U.S. by March 31, 2017, if we breach any provision of our June 2014 Equity Holders Agreement or Purchase Agreement with Mayne Pharma, if we materially breach the Supply and License Agreement and do not cure such breach within a specified time period, or if either party files for bankruptcy or insolvency proceedings.

On June 24, 2014, we and Mayne Pharma, along with Nicholas J. Virca, our President and Chief Executive Officer, Frank E. O'Donnell, Jr., M.D., our Executive Chairman, and Hedgepath, LLC consummated a series of related transactions to fulfill certain conditions of the Supply and License Agreement. In connection therewith, we and Mayne Pharma entered into an Amended and Restated Supply and License Agreement.

Securities Purchase Agreement with Mayne Pharma

On June 24, 2014, in fulfillment of one of the conditions under the Supply and License Agreement, we entered into a Securities Purchase Agreement with Mayne Pharma (which we refer to as the Mayne Purchase Agreement). Pursuant to the terms of the Mayne Purchase Agreement, we issued to Mayne Pharma (i) 258,363.280 shares of our Series A Preferred Stock, and (ii) a warrant to purchase 10,250,569 shares of our common stock. The shares of Series A Preferred Stock converted into 87,843,897 shares of common stock on August 14, 2014. Such warrant has an exercise price of $0.0878 per share and may be exercised at any time, from time to time, by Mayne Pharma prior to the expiration on June 24, 2019. As a result of the Mayne Purchase Agreement, Mayne Pharma owns approximately 40% of our equity securities on a fully diluted basis.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information concerning the ownership of the our common stock as of the date of this prospectus with respect to: (i) each person known to us to be the beneficial owner of more than five percent of our common stock; (ii) all directors; (iii) all named executive officers; and (iv) all directors and executive officers as a group. Beneficial ownership is determined in accordance with the rules of the SEC that deem shares to be beneficially owned by any person who has voting or investment power with respect to such shares. Shares of common stock subject to options or warrants that are exercisable as of the date of this prospectus or are exercisable within 60 days of such date are deemed to be outstanding and to be beneficially owned by the person holding such options for the purpose of calculating the percentage ownership of such person but are not treated as outstanding for the purpose of calculating the percentage ownership of any other person. The percentage of shares beneficially owned after the offering is based on shares of our common stock to be outstanding after the offering.

Name and address of beneficial owners	Amount and nature of beneficial ownership of Common Stock	Approximate percentage of outstanding Common Stock Prior to this Offering (1)	Approximate percentage of outstanding Common Stock After this Offering (1)
Mayne Pharma Ventures Pty Ltd.(2)	98,094,466	44.3%	%
Hedgepath, LLC(3)	114,937,638	51.9%	%
Black Robe Capital LLC(4)	114,937,638	51.9%	%
Frank E. O'Donnell, Jr., M.D.(4)	114,937,638	51.9%	%
Nicholas J. Virca(5)	—	—	—
Garrison J. Hasara, CPA(6)	—	—	—
Samuel P. Sears(7)	1,106,096	*	*
Stefan J. Cross(8)	—	—	—
Dr. R. Dana Ono(9)	—	—	—
W. Mark Watson, CPA(10)	10,000	*	*
All directors and executive officers as a group (7 persons)	116,053,734	52.4%	%

* Less than 1%

(1) Applicable percentages are based on 211,419,937 shares outstanding as of the date of this prospectus and shares outstanding following this offering. This table is based upon information supplied by officers, directors, and principal stockholders and Schedule 13G(s) filed with the SEC. Unless indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.

(2) Includes 87,843,897 shares of our common stock and a warrant to purchase an additional 10,250,569 shares of our common stock. The address for Mayne Pharma Ventures Pty Ltd is Level 14, 474 Flinders Street, Melbourne Vic 3000, Australia

(3) Includes 104,687,049 shares of our common stock and a warrant to purchase an additional 10,250,569 shares of our common stock. The address for Hedgepath LLC is 324 S Hyde Park Avenue, Suite 350, Tampa, Florida 33606

(4) The address for Black Robe Capital, LLC is 324 S Hyde Park, Suite 350, Tampa, Florida 33606. Black Robe is the sole manager of Hedgepath, LLC, and has sole voting and dispositive power over the securities held by Hedgepath, LLC. Frank E. O'Donnell, Jr., MD, our Executive Chairman, is the sole manager of Black Robe LLC, with sole voting and dispositive power over Black Robe LLC, and The Francis E. O'Donnell Jr. Irrevocable Trust No. 7 is the sole member of Black Robe LLC. Pursuant to his manager role at Black Robe, LLC, Dr. O'Donnell may be considered for SEC reporting purposes the beneficial owner of any shares held by Hedgepath, LLC. He disclaims ownership of any shares in HedgePath LLC in which he does not have a pecuniary interest.

(5) Mr. Virca is our Chief Executive Officer and President. Excludes 15,041,738 unvested restricted stock units issued under our 2014 Equity Incentive Plan. Mr. Virca's address is 700 West Harbor Drive #1104, San Diego, CA 92101.

(6) Mr. Hasara is our Chief Financial Officer and Treasurer. Excludes 7,000,000 unvested restricted stock units issued under our 2014 Equity Incentive Plan. Mr. Hasara's address is 16904 Melissa Ann Drive, Lutz, FL 33558.

(7) Mr. Sears is a director of our company. Excludes 300,000 unvested restricted stock units issued under our 2014 Equity Incentive Plan.Mr. Sears' address is 1 Fieldstone Drive, Winchester, MA. 01890.

(8) Mr. Cross is a director of our company. Excludes 300,000 unvested restricted stock units issued under our 2014 Equity Incentive Plan. Mr. Cross' address is 1240 Sugg Parkway, Greenville, NC 27834.

(9) Dr. Ono is a director of our company. Excludes 300,000 unvested restricted stock units issued under our 2014 Equity Incentive Plan. Dr. Ono's address is 18 Spring Road, Concord, MA, 01742.

(10) Mr. Watson is a director of our company. Excludes 300,000 unvested restricted stock units issued under our 2014 Equity Incentive Plan. Mr. Watson's address is 275 Bayshore Blvd., #403, Tampa, FL 33606.

DESCRIPTION OF SECURITIES

General

Our Certificate of Incorporation authorizes the issuance of up to 350,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share. As of the date of this prospectus, we had 211,419,937 shares of common stock issued and outstanding, and no shares of preferred stock issued and outstanding.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders isdetermined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters are decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our amended and restated bylaws also provide that our directors may be removed only for cause by the affirmative vote of at least sixty-six and two-thirds percent (66 2/3%) of the votes that all our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the votes that all of our stockholders would be entitled to cast in any annual election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our amended and restated bylaws*; provided, however,* that no such change to any bylaw may alter, modify, waive, abrogate or diminish the our obligation to provide the indemnity called for by Article 10 thereunder. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Our Certificate of Incorporation authorizes the issuance of 10,000,000 shares of blank check preferred stock with such designation, rights and preferences as may be determined from time to time by our board of directors. No shares of preferred stock are currently issued or outstanding as all were converted into shares of common stock as of August 14, 2014. Accordingly, our board of directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, redemption, voting or other rights which could adversely affect the voting power or other rights of the holders of common stock. We may issue some or all of the preferred stock to effect a business transaction. In addition, the preferred stock could be utilized as a method of discouraging, delaying or preventing a change in control of us.

Warrants

As of the date of this prospectus, warrants to purchase 20,501,138 shares of common stock were issued and outstanding. The warrants, issued in the amount of 10,250,569 to each of HPLLC and Mayne Pharma on June 24, 2014, have a term of 5 years and an exercise price of $0.878.

Delaware Anti-Takeover Law and Provisions of Certificate of Incorporation and By-Laws

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the Board of Directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding specified shares; or
- at or subsequent to the date of the transaction, the business combination is approved by the Board of Directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3 % of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a "business combination" to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, pledge, transfer or other disposition of 10% or more of the assets of the corporation to or with the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" as any person that is:

- the owner of 15% or more of the outstanding voting stock of the corporation;
- an affiliate or associate of the corporation who was the owner of 15% or more of the outstanding voting stock of the corporation at any time within three years immediately prior to the relevant date; or
- the affiliates and associates of the above.

Under specific circumstances, Section 203 makes it more difficult for an "interested stockholder" to effect various business combinations with a corporation for a three-year period, although the stockholders may, by adopting an amendment to the corporation's certificate of incorporation or bylaws, elect not to be governed by this section, effective 12 months after adoption.

Our certificate of incorporation and amended and restated bylaws do not exclude us from the restrictions of Section 203. We anticipate that the provisions of Section 203 might encourage companies interested in acquiring us to negotiate in advance with our Board of Directors since the stockholder approval requirement would be avoided if a majority of the directors then in office approve either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder.

Certificate of Incorporation and Amended and Restated Bylaws

On July 18, 2014, our Board of Directors approved and adopted our amended and restated bylaws. Provisions of our amended and restated bylaws and our certificate of incorporation may delay or discourage transactions involving an actual or potential change of control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our certificate of incorporation and amended and restated bylaws:

- permit our Board of Directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;

- provide that all vacancies on our Board of Directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election;
- provide that special meetings of stockholders may only be called by our Chairman and/or President, our board of directors or a super-majority (66 2/3%) of our stockholders; and
- provide that only a super-majority of our stockholders (66 2/3%) may amend our amended and restated bylaws.

SHARES AVAILABLE FOR FUTURE SALE

We cannot predict what effect, if any, market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Nevertheless, sales of substantial amounts of common stock, including shares issued upon the exercise of outstanding options or warrants, in the public market, or the perception that such sales could occur, could materially and adversely affect the market price of our common stock and could impair our future ability to raise capital through the sale of our equity or equity-related securities at a time and price that we deem appropriate.

Assuming the issuance of shares of common stock in this offering, we will have shares of common stock outstanding following this offering. Of the outstanding shares (including those sold in this offering), will be freely tradable without restriction or further registration under the Securities Act, except that any shares held by our "affiliates", as that term is defined under Rule 144, may be sold only in compliance with the limitations described below.

In addition, as of the date of this prospectus, there were 20,501,138 shares issuable upon the exercise of warrants with an exercise price of $0.878 per share, 23,541,738 shares reserved for issuance pursuant to previously granted restricted stock units and no shares issuable upon the exercise of stock options. The resale of such shares, following the exercise of such warrants by the holders thereof and the vesting of such restricted stock units, have not been registered, although we intend to register the shares underlying our EIP (including the shares underlying such restricted stock units) pursuant to a registration statement on Form S-8.

The remaining outstanding shares of common stock will be deemed "restricted securities" as that term is defined under Rule 144. Restricted securities may be sold in the public market only if they are registered or if they qualify for an exemption from registration, including the exemptions under Rule 144, which we summarize below. The restricted shares held by our affiliates will be available for sale in the public market at various times after the date of this prospectus pursuant to Rule 144.

Rule 144

Rule 144 governs resale of "restricted securities" for the account of any person (other than an issuer), and restricted and unrestricted securities for the account of an "affiliate" of the issuer. Restricted securities generally include any securities acquired directly or indirectly from an issuer or its affiliates which were not issued or sold in connection with a public offering registered under the Securities Act. An affiliate of the issuer is any person who directly or indirectly controls, is controlled by, or is under common control with, the issuer. Affiliates of ours may include its directors, executive officers, and persons directly or indirectly owning 10% or more of the outstanding common stock. Under Rule 144, non-affiliates are able to sell restricted securities pursuant to Rule 144, after six months, subject to certain conditions, including if we are current in its reporting obligations with the Commission and remains current for an additional period of six months, and thereafter after one year, with no volume or reporting obligations.

Under Rule 144, affiliates are able to sell restricted securities pursuant to Rule 144 after six months, subject to certain conditions, including if we are current in its reporting obligations with the SEC and remain current for an additional period of six months, as well as other requirements described below. Resales by our affiliates of restricted and unrestricted common stock are subject to volume limitation, aggregation, broker transaction, notice filing requirements, and requirements concerning publicly available information about our company. The volume limitations provide that a person (or persons who must aggregate their sales) cannot, within any three-month period, sell more than the greater of one percent of the then outstanding shares, or the average weekly reported trading volume during the four calendar weeks preceding each such sale.

PLAN OF DISTRIBUTION

We are offering shares of our common stock. Pursuant to an engagement letter agreement dated as of August 12, 2014, we have engaged H.C. Wainwright & Co., LLC as our placement agent for this offering. H.C. Wainwright is not purchasing or selling any shares, nor are they required to arrange for the purchase and sale of any specific number or dollar amount of shares, other than to use their commercially reasonable best efforts to arrange for the sale of shares by us. Subject to the terms and conditions of the engagement letter agreement, the placement agent is using its commercially reasonable best efforts to introduce us to selected institutional investors. Therefore, we may not sell the entire amount of shares being offered.

Additionally, pursuant to our June 2014 Equity Holders Agreement, we have granted Mayne Pharma and its affiliates a right of first refusal to purchase a pro rata share of any new securities issued by us. This right allows Mayne Pharma and its affiliates to purchase such pro rata share to be determined based upon the number of shares of our common stock held by Mayne Pharma and its affiliates on a fully diluted basis as compared to the number of shares of common stock outstanding immediately prior to the offering of the new securities on a fully diluted basis. As a result, Mayne Pharma and its affiliates may choose to acquire the securities issued pursuant to this offering.

Upon the closing of this offering, we will pay the placement agent a cash transaction fee equal to eight percent (8%) of the gross proceeds to us from the sale of the shares of common stock in the offering, provided that, with regard to shares purchased by Mayne Pharma, we will pay the placement agent a cash fee equal to four percent (4%) of the aggregate amount of such shares purchased by Mayne Pharma. We will also pay the placement agent a non-accountable expense allowance of $125,000, $15,000 of which has been previously paid and the balance of which will be due upon the closing of the offering. We estimate expenses payable by us in connection with this offering, other than the placement agent fees referred to above, will be approximately $.

In addition, we have agreed to grant the placement agent a warrant to purchase shares of our common stock equal to four percent (4%), or in the case of Mayne Pharma, three percent (3%) of the aggregate number of shares of common stock sold to such investors in this offering. These placement agent warrants will be exercisable for a period of five years and will have an exercise price equal to 110% of the offering price per share. We are registering the placement agent warrant and the shares of common stock issuable upon exercise of such warrant. The placement agent warrant will have the same terms as the warrants issued to investors in the offering. Pursuant to the Financial Industry Regulatory Authority, or FINRA, Rule 5110(g), neither the placement agent warrant nor any shares issued upon exercise of the placement agent warrant shall be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security:

- by operation of law or by reason of reorganization of our company;
- to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period;
- if the aggregate amount of securities of our company held by the holder of the placement agent warrant or related person do not exceed 1% of the securities being offered;
- that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or
- the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period.

We have granted the placement agent a right of first refusal in future financings to act as lead underwriter, lead book runner or lead placement agent (provided that in no event shall such right extend beyond the 12-month anniversary of the effective date of this registration statement).

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any commissions received by it and any profit realized on the sale of the securities by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent will be required to comply with the requirements of the Securities Act and the Securities Exchange Act of 1934, as amended, or the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

We and our directors, officers and substantially all of our stockholders have agreed not to offer, sell, contract to sell or grant any option to sell or otherwise dispose of any shares of our common stock or other securities convertible into or exchangeable or exercisable for shares of our common stock or derivatives of our common stock prior to this offering or common stock issuable upon exercise of options or warrants for a period of 180 days after the effective date of this registration statement.

There are no agreements between us and the placement agent releasing us or our directors, officers and principal stockholders from this lock-up prior to the expiration of this period. Notwithstanding our lock-up agreement with the placement agent, we may issue warrants, options and shares of capital stock in connection with the exercise of warrants and options outstanding prior to the closing of this offering and the grant of options to our officers, directors, employees and consultants under our equity incentive plan.

The engagement letter agreement provides that we will indemnify the placement agent against specified liabilities, including liabilities under the Securities Act. We have been advised that, in the opinion of the Securities and Exchange Commission, indemnification for liabilities under the Securities Act is against public policy as expressed in the Securities Act and is therefore unenforceable.

Notice to Certain Investors

European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, or the Relevant Implementation Date, no offer of any securities which are the subject of the offering contemplated by this prospectus has been or will be made to the public in that Relevant Member State other than any offer where a prospectus has been or will be published in relation to such securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the relevant competent authority in that Relevant Member State in accordance with the Prospectus Directive, except that with effect from and including the Relevant Implementation Date, an offer of such securities may be made to the public in that Relevant Member State:

(a) to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;

(b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of securities shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

[Table of Contents](#)

United Kingdom

The communication of this prospectus and any other documents or materials relating to this prospectus is not being made and such documents and/or materials have not been approved by an authorized person for the purposes of section 21 of the Financial Services and Markets Act 2000. In the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the “Order”) and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons.

Table of Contents

LEGAL MATTERS

Certain legal matters with respect to the shares of common stock offered hereby will be passed upon by Ellenoff Grossman & Schole LLP, New York, New York. The placement agent is being represented by Mintz, Levin, Cohn, Ferris,Glovsky and Popeo, P.C., Boston, Massachusetts.

EXPERTS

The financial statements of our company appearing in this prospectus have been included herein in reliance upon the report (which report includes an explanatory paragraph relating to our ability to continue as a going concern) of Cherry Bekaert LLP, an independent registered public accounting firm, appearing elsewhere herein, and upon the authority of Cherry Bekaert LLP as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1 with the Securities and Exchange Commission (SEC) for our common stock offered in this offering. This prospectus does not contain all of the information set forth in the registration statement. You should refer to the registration statement and its exhibits for additional information. Whenever we make references in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete and you should refer to the exhibits attached to the registration statement for the copies of the actual contract, agreement or other document.

Our fiscal year ends on December 31. We are a reporting company and file annual, quarterly, and current reports, and other information with the SEC. You may read and copy any reports, statements, or other information we file at the SEC's public reference room at 100 F. Street, N.E., Washington D.C. 20549. You can request copies of these documents, upon payment of a duplicating fee by writing to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference rooms. Our SEC filings are also available to the public on the SEC's Internet site at http://www.sec.gov. We maintain a website at www.hedgepathpharma.com. Information contained in or accessible through our website is not and should not be considered a part of this prospectus and you should not rely on that information in deciding whether to invest in our common stock.

[Table of Contents](#)

HEDGEPATH PHARMACE UTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors of HedgePath Pharmaceuticals, Inc.

We have audited the accompanying balance sheet of HedgePath Pharmaceuticals, Inc. (the "Company") as of December 31, 2013 and the related statements of operations, stockholders' (deficit) equity and cash flows for the year then ended. The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with standards of the Public Company Accounting Oversight Board (United States of America). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis of designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of HedgePath Pharmaceuticals, Inc. as of December 31, 2013 and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company incurred cumulative net losses since inception of approximately $28 million, of which approximately $1.5 million was incurred subsequent to the emergence from bankruptcy, as discussed in Note 1. Furthermore, the Company expects to continue to incur net losses through the foreseeable future and has significant negative working capital at December 31, 2013. These factors, among others as discussed in Note 2 to the financial statements, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Cherry Bekaert LLP

Tampa, Florida
April 15, 2014

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
HedgePath Pharmaceuticals, Inc.
(as successor to Commonwealth Biotechnologies, Inc.)
Tampa, FL

We have audited the accompanying balance sheet of HedgePath Pharmaceuticals, Inc. (as successor to Commonwealth Biotechnologies, Inc.) as of December 31, 2012 and the related statements of operations, stockholders' deficit, and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of HedgePath Pharmaceuticals, Inc. (as successor to Commonwealth Biotechnologies, Inc.) as of December 31, 2012 and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company's recurring losses from operations and inability to generate sufficient cash flow to meet its obligations and sustain its operations raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also discussed in Note 2 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PBMares, LLP

Richmond, Virginia
May 13, 2013

Table of Contents

HEDGEPATH PHARMACEUTICALS, INC.
BALANCE SHEETS
DECEMBER 31, 2013 AND 2012

	December 31, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 217	$ 857,702
Other current assets	—	78,733
Prepaid assets	10,000	—
Total current assets	10,217	936,435
Total assets	$ 10,217	$ 936,435
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 287,072	$ 368,613
Notes payable, related party	68,428	—
Accrued payroll liabilities	—	191,340
Other liabilities	52,500	—
Accrued interest	1,923	—
Due to related party	366,130	—
Total current liabilities	776,053	559,953
Liabilities subject to compromise:		
Priority claims	—	23,450
Accounts payable and other unsecured creditors	—	422,316
Other liabilities	—	63,500
Total liabilities subject to compromise	—	509,266
Total liabilities	776,053	1,069,219
Commitments and contingencies (note 4)	—	—
Stockholders' deficit:		
Series A Preferred Stock, $0.0001 par value; 500,000 and no shares authorized in 2013 and 2012, respectively; 170,001 and no shares issued and outstanding in 2013 and 2012, respectively.	17	—
Undesignated Preferred Stock, $0.0001 par value in 2013 and no par value in 2012. 9,500,000 and 1,000,000 shares authorized in 2013 and 2012, respectively; no shares issued or outstanding in 2013 and 2012.	—	—
Common Stock, $0.0001 par value in 2013 and no par value in 2012; 340,000,000 and 100,000,000 shares authorized in 2013 and 2012, respectively; 18,888,971 and 15,560,504 shares issued and outstanding in 2013 and 2012, respectively	1,889	—
Additional paid-in capital	27,479,913	26,279,815
Accumulated deficit	(28,247,655)	(26,412,599)
Total stockholders' deficit	(765,836)	(132,784)
Total liabilities and stockholders' deficit	$ 10,217	$ 936,435

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2013 AND 2012

	Year Ended December 31,	
	2013	2012
Revenues:	$ —	$ —
Total revenues	—	—
Expenses:		
Chapter 11 expenses	117,324	—
Research and development	1,065,169	—
General and administrative	817,316	560,670
Total expenses	1,999,809	560,670
Loss from operations	(1,999,809)	(560,670)
Interest expense	(1,923)	—
Gain on reorganization:		
Realized gains	—	80,369
Gain on extinguishment of debt	—	666,667
Gain on settlement of pre-petition claims	166,676	—
	166,676	747,036
Net (loss) income	$ (1,835,056)	$ 186,366
Basic and diluted (loss) earnings per share	$ (0.10)	$ 0.01
Weighted average common stock shares outstanding	17,940,586	13,646,638

See notes to financial statements

[Table of Contents](#)

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF STOCKHOLDERS' DEFICIT
YEARS ENDED DECEMBER 31, 2013 AND 2012

	Preferred Stock Series A		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balances, January 1, 2012	—	$ —	12,660,504	$ —	$26,229,815	$(26,598,965)	$ (369,150)
Issuance of common stock	—	—	2,900,000	—	50,000	—	50,000
Net income	—	—	—	—	—	186,366	186,366
Balances, December 31, 2012	—	—	15,560,504	—	$26,279,815	$(26,412,599)	$ (132,784)
Issuance of preferred stock pursuant to the contribution agreement	170,001	17	—	—	1,049,987	—	1,050,004
Issuance of restricted stock in lieu of cash payment under the Bankruptcy Plan	—	—	3,328,467	—	152,000	—	152,000
Initiation of par value pursuant to agreement and plan of merger and reorganization	—	—	—	1,889	(1,889)	—	—
Net loss	—	—	—	—	—	(1,835,056)	(1,835,056)
Balances, December 31, 2013	170,001	$ 17	18,888,971	$ 1,889	$27,479,913	$(28,247,655)	$ (765,836)

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2013 AND 2012

	Year Ended December 31, 2013	Year Ended December 31, 2012
Operating activities:		
Net (loss) income	$(1,835,056)	$ 186,366
Adjustments to reconcile net (loss) income to net cash flows from operating activities:		
In-process research and development purchased with the issuance of preferred stock	1,020,004	—
Unrealized loss on investments	—	527
Gain on extinguishment of debt	—	(666,667)
Expenses paid with the issuance of stock	—	50,000
Changes in assets and liabilities:		
Other current assets	68,733	—
Accounts payable and other current liabilities	46,645	(34,492)
Net cash flows from operating activities before reorganization items	(699,674)	(464,266)
Reorganization items:		
Gain on reorganization	(166,676)	—
Decrease in liabilities subject to compromise	(357,265)	—
Net cash flows from operating activities	(1,223,615)	(464,266)
Financing activities:		
Proceeds from related party advances	366,130	—
Net cash flows from financing activities	366,130	—
Net change in cash and cash equivalents	(857,485)	(464,266)
Cash and cash equivalents at beginning of period	857,702	1,321,968
Cash and cash equivalents at end of period	$ 217	$ 857,702
Supplemental disclosure of non-cash financing activity:		
Reclassification of deposit to additional paid-in capital	$ 30,000	$ —
Promissory notes issued in payment of related party obligations	$ 68,428	$ —
Stock payments to officers and directors (liabilities subject to compromise) in lieu of cash payments under the Bankruptcy Plan	$ 152,000	$ —
Expenses satisfied with the issuance of stock	$ —	$ 50,000
Gain on extinguishment of debt	$ —	$ 687,500

See notes to financial statements

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

1. Corporate overview:

Overview

The accompanying audited financial statements of HedgePath Pharmaceuticals, Inc., a Delaware corporation (the "Company", "HPPI", "we", "us" or similar terminology) as successor to Commonwealth Biotechnologies, Inc., a Virginia corporation ("CBI"), have been prepared by the Company as a going concern.

As used herein, the term "Common Stock" means the Company's common stock, $0.0001 par value per share.

Nature of the Business

CBI was a specialized life sciences outsourcing business that offered certain peptide-based discovery chemistry and biology products and services through Mimotopes Pty Limited ("Mimotopes"), a wholly-owned subsidiary of CBI. On January 20, 2011, CBI filed a voluntary petition captioned *In re Commonwealth Biotechnologies, Inc., Case No. 11-30381-KRH* (the "Chapter 11 case") in the United States Bankruptcy Court for the Eastern District of Virginia (the "Bankruptcy Court") seeking relief under the provisions of Chapter 11 of Title 11 of the United States Code (the "Bankruptcy Code"). On April 7, 2011, the Bankruptcy Court approved the private sale of the Mimotopes business unit for a net sales price of $850,000. The sale closed on April 29, 2011.

On August 12, 2013, in furtherance of CBI's emergence from bankruptcy as described further below, CBI effected a "short-form" reincorporation merger with HPPI, a newly created and wholly owned Delaware subsidiary of CBI, pursuant to which CBI merged with and into HPPI, with HPPI surviving the merger and with the effect of CBI becoming reincorporated as a Delaware corporation and changing its corporate name. Each outstanding share of CBI was converted into one share of HPPI. HPPI's Certificate of Incorporation (and thus the Certificate of Incorporation of the surviving company) authorizes the issuance of up to 340,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share. The par value was changed from no par value to $0.0001, which par value is customary for newly formed Delaware corporations.

As described further below, the Company's present business is the development of the currently-marketed drug itraconazole (currently approved by the U.S. Food and Drug Administration ("FDA") as an anti-fungal agent) for the treatment of certain cancers.

Pre-Bankruptcy and Emergence from Bankruptcy

On January 4, 2013, CBI filed an Amended Plan of Reorganization (the "Plan") with the Bankruptcy Court. The Plan was approved by a vote of creditors and CBI stockholders on March 21, 2013. CBI received an auction fee of $30,000 from Hedgepath, LLC, a Florida limited liability company, (which fee was a binding, irrevocable offer for the purchase of a portion of CBI's equity interests) in addition to the contribution of Assets as described below. Hedgepath, LLC was the winning bidder for CBI, which is more fully described below in *Post-Bankruptcy Business of HPPI-General.* This auction fee was recognized as an increase in additional paid-in capital when the Contribution Agreement (as defined below) became effective.

On March 29, 2013, the Bankruptcy Court entered an order (the "Confirmation Order") confirming the Plan pursuant to Chapter 11 of the Bankruptcy Code. Under the terms of the Plan, and pursuant to the Contribution Agreement (as described further below), Hedgepath, LLC contributed and assigned the Assets (as such term is defined below) to HPPI, as the reorganized debtor, in exchange for the right to receive 90% of fully diluted voting equity in HPPI (in the form of the Series A Preferred Stock) on the date of issuance, with the prior stockholders of CBI retaining approximately 10% voting equity in HPPI, represented by 100% of the issued and outstanding shares of Common Stock.

Contribution Agreement

On August 13, 2013, the Company entered into a Contribution Agreement, dated as of August 13, 2013 (the "Contribution Agreement"), by and between the Company and Hedgepath, LLC pursuant to which, and subject to the terms and conditions contained therein, in exchange for the right to receive 170,001 shares of the Company's newly created Series A Convertible Preferred Stock (the "Series A Preferred Stock"), representing 90% of the fully diluted voting securities of the Company as of the date of issuance (or 170,000,739 shares of Common Stock on an as converted basis), Hedgepath, LLC contributed and/or assigned various assets and contract rights to the Company associated with the going forward business of the Company (collectively, the "Assets") to the Company as described below.

(i) U.S. Provisional Patent Application 61-813,122, "Prostate-Specific Antigen as Biomarker for Hedgehog Pathway Inhibitor Treatment and Prognostic Monitoring of Prostate Cancer" (previously assigned to Hedgepath, LLC by Dr. Frank E. O'Donnell, Jr. and Nicholas J. Virca, as inventors);

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

1. Corporate overview (continued):

(ii) U.S. Provisional Patent Application 61-813,823, "Treatment and Prognostic Monitoring of Cancer Using Hedgehog Pathway Inhibitors" (previously assigned to Hedgepath, LLC by Dr. Frank E. O'Donnell, Jr. and Nicholas J. Virca, as inventors);

(iii) Assignment of Patents, dated November 1, 2012, by Dr. Frank E. O'Donnell, Jr. in favor of Hedgepath, LLC;

(iv) Assignment of Patents, dated November 1, 2012, by Nicholas J. Virca in favor of Hedgepath, LLC;

(v) Consulting Agreement, dated and effective as of September 1, 2012, by and between HPPI (as successor to Hedgepath, LLC) and Emmanuel Antonarakis, MD ("Antonarakis").

(vi) Confidentiality and Intellectual Property Assignment Agreement, dated and effective September 1, 2012, between Antonarakis and HPPI (as successor to Hedgepath, LLC), which includes all intellectual property, know-how and other assets assigned to Hedgepath, LLC by Antonarakis under such agreement.

(vii) Consulting Agreement, effective as of April 11, 2013, by and between Hedgepath, LLC and Arianne Consulting, Inc. ("Arianne"); and

(viii) Confidentiality and Intellectual Property Assignment Agreement, dated and effective April 11, 2013, between Arianne and Hedgepath, LLC , which includes all intellectual property, know-how and other assets assigned to Hedgepath, LLC by Arianne under such agreement.

The Contribution Agreement was entered into to carry out the purposes and intent of the Plan filed by CBI and confirmed by the Bankruptcy Court in connection with the Chapter 11 case.

Hedgepath, LLC is a development stage pharmaceutical company. Since its formation in late 2011, Hedgepath, LLC has sought, among other pharmaceutical business opportunities, to acquire technology rights and to conduct activities related to the development of the currently-marketed drug itraconazole (currently FDA approved as an anti-fungal agent) for the treatment of certain cancers (the "Itra Business Opportunity"). Hedgepath, LLC has expended approximately $0.1 million acquiring assets and developing the ITRA Business Opportunity including approximately $82,500 on technical and medical consulting and $15,000 on option fees related to intellectual property agreement that has since expired.

In accordance with the Plan, and as a result of the transactions contemplated by the Contribution Agreement, from and after August 13, 2013, HPPI will be engaged in the Itra Business Opportunity. The Assets contributed to the Company by Hedgepath, LLC represent the assets and rights heretofore developed or acquired by Hedgepath, LLC related to the Itra Business Opportunity, and by virtue of the Contribution Agreement, the Company acquired all of Hedgepath, LLC's right, title and interest in and to the Assets.

As part of the Contribution Agreement, Hedgepath, LLC, which owned a certain claim against CBI in the amount of $52,500, payable to a third party service provider, contributed such claim to the Company. HPPI has agreed to issue to such service provider a number of restricted shares of its Common Stock to be determined based on the valuation of the shares to be issued to purchasers in connection with HPPI's planned $5 million offering of securities as described in the Plan. Such shares of Common Stock are to be issued to such service provider within five (5) business days of the final determination of such valuation (as memorialized in the final transaction documentation for such offering).

Hedgepath, LLC did not contribute any of its liabilities to the Company in connection with the Contribution Agreement, and retained all of its assets other than those related to the Itra Business Opportunity.

In conjunction with the execution of the Contribution Agreement, the Company has expensed, as in-process research and development cost, approximately $1.0 million. The value was calculated by taking 90% of the market capitalization on the date the assets were contributed to reflect the 90% ownership exchanged for the assets contributed by Hedgepath, LLC.

Post-Bankruptcy Business of HPPI—General

As a result of the aforementioned transactions, as of August 13, 2013 the Company is a clinical stage biopharmaceutical company that endeavors to discover, develop and commercialize innovative therapeutics for patients with certain cancers. The Company is currently

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

1. Corporate overview (continued):

focused on the development of therapies for certain cancers, with initial emphasis on skin, prostate and lung cancers in the U.S. market, based upon the use of the currently marketed anti-fungal drug itraconazole. The Company believes that itraconazole could affect the Hedgehog signaling pathway in cells, a major regulator of many fundamental cellular processes, which could, in turn, impact the development and growth of certain cancers.

Itraconazole is FDA approved for and extensively used to treat fungal infections and has an extensive history of safe and effective use in humans. The Company has developed, optioned and is seeking to acquire and/or license, intellectual property and know-how related to the treatment of cancer patients using itraconazole and has applied for patents to cover the Company's inventions.

Net (loss) income per common share

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings per common share computations for the years ended December 31, 2013 and 2012.

	2013	2012
Basic:		
Net (loss) income attributable to common stockholders	$ (1,835,056)	$ 186,366
Weighted average common shares outstanding	17,940,586	13,646,638
Basic (loss) earnings per common share	$ (0.10)	$ 0.01
Diluted:		
Effect of dilutive securities:		
Net (loss) income attributable to common stockholders	$ (1,835,056)	$ 186,366
Adjustments to income for dilutive options and warrants	—	—
	(1,835,056)	186,366
Weighted average common shares outstanding	17,940,586	13,646,638
Effect of dilutive options and warrants	—	—
Diluted weighted average common shares outstanding	17,940,586	13,646,638
Diluted (loss) earnings per common share	$ (0.10)	$ 0.01

Basic earnings per common share is calculated using the weighted average shares of Common Stock outstanding during the period. Common equivalent shares from stock options and warrants using the treasury stock method, are also included in the diluted per share calculations unless the effect of inclusion would be antidilutive. During the year ended December 31, 2012, outstanding stock options and warrants of 1,220,443 were not included in the computation of diluted earnings per common share, because to do so would have had an antidilutive effect because the outstanding exercise prices were greater than the average market price of the common shares during the relevant periods.

2. Liquidity and management's plans:

A continued lack of adequate cash resulting from the Company's bankruptcy, the sale of CBI's principal assets, and the resulting inability to generate cash flow from operations or to raise capital from external sources forced the Company to substantially curtail or cease operations and, therefore, had a material adverse effect on its business. Consequently, during 2012 and 2013, the Company's business has undergone substantial reductions in relation to size, scale and scope of activities.

As a result of the foregoing circumstances, there is substantial doubt about the Company's ability to continue as a going concern. The Company's previous and current independent auditors have included a paragraph emphasizing "going concern" uncertainty in their report on the 2012 and 2013 financial statements. The financial statements included herein do not include any adjustments relating to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should the Company be unable to continue as a going concern.

The Company currently has cash and cash equivalents of $217 as of December 31, 2013, and has and will therefore rely on loans from insiders and affiliates to fund its operations until the Company is able to raise additional capital. Subsequent to December 31, 2013, working capital advances as of the date of this Report from Hedgepath, LLC amounted to approximately $100,000, and have been used for officer and employee salaries, legal and professional fees.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

2. Liquidity and management's plans (continued):

The Company intends to finance its research and development, commercialization and distribution efforts and its working capital needs primarily through:

- partnering with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive upfront milestone and royalty payments;
- licensing and joint venture arrangements with third parties, including other pharmaceutical companies where the Company would receive funding based on out-licensing its product to augment their product profile in the treatment of cancers;
- receiving government or private foundation grants which would be awarded to the Company to further develop our current and future anti-cancer therapies; and
- securing proceeds from public and private financings and other strategic transactions.

However, there can be no assurance that any of these plans will be implemented on commercially reasonable terms, if at all.

3. Summary of Significant Accounting Policies:

Recent accounting pronouncements

In July 2013, the FASB issued ASU 2013-11– Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists ("ASU 2013-11"). This guidance requires the unrecognized tax benefit to be presented in the financial statements as a reduction to a deferred tax asset. When a deferred tax asset is not available, or the asset is not intended to be used for this purpose, an entity should present the unrecognized tax benefit in the financial statements as a liability. The guidance will become effective for us at the beginning of our first quarter of fiscal 2014. The Company does not expect the adoption of this guidance will have a material impact on its financial statements.

In January 2013, the FASB issued ASU 2013-01 – Clarifying the Scope of Disclosures about Offsetting Assets and Liabilities ("ASU 2013-01"). The amended guidance limits the scope of balance sheet offsetting disclosures to derivatives, repurchase agreements, and securities lending transactions to the extent that they are offset in the financial statements or subject to an enforceable master netting arrangement or similar agreement. The guidance became effective for us at the beginning of our fourth quarter of fiscal 2013. The adoption of this guidance had no impact on the Company's financial statements.

Estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

Revenue Recognition

The Company currently has no ongoing source of revenues. Any miscellaneous income is recognized when earned by the Company.

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. At times, the Company may maintain cash balances in excess of Federal Deposit Insurance Corporation insured amounts.

Research and Development Expenses

Research and development costs are expensed in the period in which they are incurred and include the expenses paid to third parties who conduct research and development activities on behalf of the Company.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

3. Summary of Significant Accounting Policies (continued):

Accounting for Enterprises in Reorganization

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 852—*Reorganizations* ("ASC Topic 852"), which is applicable to companies in Chapter 11, generally does not change the manner in which financial statements are prepared. However, it does require that the financial statements for periods subsequent to the filing of the Chapter 11 petition distinguish transactions and events that are directly associated with the reorganization from the ongoing operations of the business. Revenues, expenses, realized gains and losses, and provisions for losses that can be directly associated with the reorganization and restructuring of the business must be reported separately as reorganization items in the statements of operations beginning in the quarter ending March 31, 2011. The balance sheet must distinguish prepetition liabilities subject to compromise from both those prepetition liabilities that are not subject to compromise and from post-petition liabilities. Liabilities that may be affected by a plan of reorganization must be reported at the amounts expected to be allowed by the Bankruptcy Court, even if they may be settled for lesser amounts. In addition, cash flows from reorganization items must be disclosed separately in the statement of cash flows. The Company became subject to ASC Topic 852 effective on January 20, 2011, and has segregated those items as outlined above for all reporting periods after such date. The Company officially emerged from bankruptcy on April 17, 2013, followed by the reincorporation merger, which satisfied the final condition to effectiveness of the Plan as detailed in Note 1.

Income taxes

Deferred tax assets and liabilities are recognized for future tax consequences attributed to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and are measured using enacted tax rates that are expected to apply to the differences in the periods that they are expected to reverse. Management has evaluated the guidance relating to accounting for uncertainty in income taxes and has determined that the Company had no uncertain income tax positions that could have a significant effect on the consolidated financial statements for the years ended December 31, 2013 or 2012.

4. Supply and License Agreement

On September 3, 2013, the Company entered into an exclusive Supply and License Agreement (the "Supply and License Agreement") with Mayne Pharma International Pty Ltd., a company incorporated in Australia ("Mayne Pharma"), pursuant to which Mayne Pharma agreed to: (i) supply the Company with its patented formulation of the drug itraconazole, known as SUBA™-Itraconazole, in a particular dose formulation (the "Product") for the treatment of human patients with cancer via oral administration (the "Field") (with the initial areas of investigation being prostate, lung and skin cancer) in the United States (the "Territory"), (ii) provide the Company with an exclusive license to use and develop the intellectual property related to the Product in the Field and in the Territory and (iii) participate in a joint development committee with the Company ("JDC") to clinically develop the Product in the Field and in the Territory. The Company will pursue the development of the Product for treatment of a variety of cancers with a focus on clinical development, seeking regulatory approvals and, if regulatory approval is obtained, marketing in the United States.

Pursuant to the Supply and License Agreement, the Company, with the assistance of Mayne Pharma through the JDC and subject to certain approval rights of Mayne Pharma, will develop and exploit the Product through a development plan which will be authorized by the JDC and updated as necessary. The license granted to the Company under the Supply and License Agreement may only be assigned or sub-licensed with the prior approval of Mayne Pharma. In addition, in support of the exclusive nature of the Supply and License Agreement, during the term, Mayne Pharma is prohibited from directly or indirectly importing, promoting, marketing, distributing or selling the Product in the Territory and in the Field. If any other form of the Product manufactured by Mayne Pharma is sold as a result of any off label use, the Company shall be entitled to a royalty on such off-label sales. Further, the Company may not develop products that are competitive with the Product, which period extends for a certain period following the end of the term.

Under the Supply and License Agreement, the Company is responsible for obtaining all of its requirements for the Product from Mayne Pharma, including for use in clinical trials, importation, promotion, marketing, sale and distribution in the Territory. The Company and Mayne Pharma have established certain minimum floor prices that the Company must pay per unit of the Product and minimum order quantities for the Product.

Any intellectual property created by the Company, either on its own or jointly with Mayne Pharma, relating to the Product in the Field will be owned by the Company, except that the Company has granted Mayne Pharma an exclusive, perpetual, irrevocable, royalty free license to copy and exploit such developed intellectual property outside of the Territory.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

4. Supply and License Agreement (continued):

Although the Supply and License Agreement is effective immediately, it remained subject to early termination by Mayne Pharma if certain conditions (the "Conditions") were not met by December 16, 2013. Such Conditions include: (i) the Company shall have raised $5 million in an equity financing (or such lesser amount as may be agreed to by Mayne Pharma) (the "Equity Financing"); (ii) a representative of Mayne Pharma shall have been appointed to the Company's board of directors, and Mayne Pharma and the Company shall have entered into an agreement granting Mayne Pharma certain board appointment rights; (iii) Mayne Pharma shall, pursuant to customary definitive documentation to be negotiated by the parties, acquire from the Company, as part of the consideration under the Supply and License Agreement, 170,001 shares of the Company's Series A Preferred Stock, par value $0.0001 per share (the "Series A Preferred Stock"), representing, on an as fully converted, fully diluted basis, 45% of the issued and outstanding shares of capital stock of the Company (prior to the Equity Financing (as defined below) and the anticipated adoption by the Company of an equity incentive plan); (iv) Hedgepath, LLC (an affiliate of the Company who currently has the right to receive shares of Series A Preferred Stock), Nicholas J. Virca (the Company's President and Chief Executive Officer) ("Virca") and Mayne Pharma shall have entered into an agreement providing for certain restrictions on transfers and ownership of Company equity; (v) the Company and Mayne Pharma shall have entered into an agreement granting Mayne Pharma and accredited investors introduced to the Company by Mayne Pharma certain participation rights in future Company equity financings; (vi) the Company shall have (a) received a written estimate from a credible contract research organization reasonably acceptable to Mayne Pharma relating to the Company's proposed clinical trials and (b) provided reasonable assurances to Mayne Pharma that the Product will be available for commercial launch by a specified date; and (vii) Virca and Frank E. O'Donnell, Jr., the Company's Executive Chairman, shall have entered into customary agreements regarding their positions with the Company. Due to the contingent nature of the Supply and License Agreement, none of Series A Preferred Stock has been issued to Mayne Pharma as of the date of this Report and, therefore, there is no accounting treatment applicable.

Subject to earlier termination if the Conditions are not met as described above, the term of the Supply and License Agreement shall last until the later of: (i) 10 years from the target launch date of the Product for the treatment of human patients with cancer via oral administration or (ii) the date on which all issued patents of Mayne Pharma or any of its affiliates referred to in the Supply and License Agreement have lapsed or expired.

The Supply and License Agreement is further subject to termination in certain circumstances, including: (i) by either party in the event of (a) a material default that is not cured within a specified number of days after notice is received or is not capable of remedy, (b) if marketing authorizations for the Product are not obtained prior to the agreed upon target launch date for the Product or (c) a force majure event precluding performance by the other party for a specified period of time, (ii) the voluntary or involuntary bankruptcy of either party, (iii) by Mayne Pharma if either Hedgepath, LLC or Virca breach their respective agreements with Mayne Pharma to restrict the sale and or transfer of their shares of Company equity and such breach is not cured within a specified number of days after notice is received or such breach is not capable of remedy, (iv) by Mayne Pharma if the Company breaches certain of its obligations relating to the Conditions (once they are satisfied) and such breach is not cured within a specified number of days after notice is received or such breach is not capable of remedy, (v) by Mayne Pharma if, under certain circumstances, the Company fails to purchase the minimum agreed upon amounts of Product in any given year or (vi) by Mayne Pharma, under certain circumstances, upon a change of control of the Company.

On December 17, 2013, the Company entered into Amendment No. 1 to the Supply and License Agreement (the "Amended Supply and License Agreement") with Mayne Pharma. The Amended Supply and License Agreement amends the Agreement as follows:

(i) the date by which the Conditions (as defined below) must be met was extended from December 16, 2013 to February 28, 2014;

(ii) Mayne Pharma had agreed to reimburse all reasonable third party expenses incurred in the conduct of the activities set out in, and in accordance with, the development plan as set forth in the Agreement (the "Development Plan"), or otherwise related to the Product by the Company from the date of the Amended Supply Agreement through February 28, 2014; provided however that (i) such expenses may not exceed $100,000, (ii) the Company must receive prior written approval from Mayne Pharma prior to incurring such expenses, and (iii) any third party engaged to provide clinical or other services to the Company must first enter into an agreement with the Company to assign all intellectual property rights developed by or on behalf of it in providing such services to the Company. Furthermore, such reimbursement must be repaid by the Company to Mayne Pharma once the Conditions have been met or waived by Mayne Pharma; and

(iii) if Mayne Pharma terminated the Agreement, then the Company will assign to Mayne Pharma all intellectual property rights created or developed in the conduct of the activities set out in, and in accordance with, the Development Plan or

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

4. Supply and License Agreement (continued):

otherwise related to the Product that have been created or developed between the date of the Amended Supply and License Agreement and February 28, 2014. Such assignment will occur whether such rights were created or developed by or on behalf of the Company, its affiliates or any third party providing services to the Company or its affiliates; provided however, that: (i) all rights of the Company in the HP Patents (as defined in the Agreement) and all intellectual property rights of the Company created or developed (either by the Company or jointly with Mayne Pharma) prior to the date of the Amended Supply and License Agreement shall remain the exclusive property of the Company as provided for in the Agreement and (ii) if the Conditions have been waived by Mayne Pharma or satisfied as of or prior to the February 28, 2014, all provisions of the Agreement relating to the ownership of intellectual property rights relating to the Product shall be governed by the original provisions of the Agreement and this provision will be terminated upon the waiver by Mayne Pharma, or satisfaction, of the Conditions.

As provided for in the Agreement, as amended, Mayne Pharma could have terminated the Agreement since certain conditions were not met by February 28, 2014.

On March 5, 2014, the Company entered into Amendment No. 2 to the Supply and License Agreement (the "Amended Supply and License Agreement") with Mayne Pharma. The Amended Supply and License Agreement amends the Agreement as follows:

(i) the date by which the Conditions (as defined below) must be met was extended from February 28, 2014 to March 31, 2014;

(ii) the Company has agreed to use reasonable efforts to progress the conduct of the activities set out in, and in accordance with, the development plan as set forth in the Agreement (the "Development Plan"), and to seek reimbursement of relevant amounts in accordance with the Agreement;

(iii) the Company and Mayne Pharma acknowledged and agreed that warrants may be issued in connection with an Equity Financing (as defined below) and further agreed that in the event that warrants are issued in connection with an Equity Financing, Mayne Pharma will receive a warrant on the same terms as the warrants issued in the Equity Financing for such a number of shares that will ensure that Mayne Pharma will hold at least 30% of the issued and outstanding shares of capital stock of the Company on a fully diluted, fully converted basis following the Equity Financing;

(iv) if the Company does not (i) submit a complete Investigational New Drug ("IND") application to the United States Food and Drug Administration (the "FDA") for the Product for at least one indication in the Field and commence dosing patients in at least two phase II or phase II/III clinical trials across at least two indications in the Field by March 31, 2015 or (ii) submit an application for a new drug application to the FDA for at least one indication by March 31, 2016, then Mayne Pharma may, by notice to Frank E. O'Donnell, Jr. M.D., the Company's Executive Chairman, and Nicholas J. Virca, the Company's President and Chief Executive Officer, require each of them to resign from the Company, in which case each of Hedgepath LLC, Mr. Virca and Dr. O'Donnell will forfeit all of their respective unvested Company options, and Mayne Pharma will have the right to purchase all issued and outstanding shares of the Company's capital stock held by Mr. Virca and Dr. O'Donnell at market price, and neither Mr. Virca nor Dr. O'Donnell will be entitled to receive any severance or similar payments from the Company;

(v) in the event that Dr. O'Donnell or Mr. Virca are removed or resign from the Company's board of directors, any replacement appointees will need to obtain unanimous approval from the remaining board members; and

(vi) Mayne Pharma waived its right to require the Company to obtain a written estimate from a contact research organization relating to the timing and completion of phase II trials on the use of the Product in the Field and waived its right to reasonably expect that the Product would launch by a date agreed upon the Company and Mayne.

Mayne Pharma could have terminated the Agreement, as amended, if certain conditions were not met by March 31, 2014. That date was extended to April 25, 2014 by mutual agreements. The Company is continuing efforts to meet those conditions. No transactions under the original or amended Supply and License Agreement have transpired to date.

5. Gain on Reorganization:

The Company has recognized gains of $166,676 and $747,036, which are included in gain on reorganization in the accompanying statements of operations for the years ended December 31, 2013 and 2012, respectively, as a result of final payments under the Chapter 11 reorganization plan.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

6. **Debt:**

On September 4, 2008, CBI completed the issuance of a $500,000 convertible promissory note ("the Note") payable to Fornova Pharmaworld, Inc. ("the Holder"). On February 10, 2012, the CBI filed a claim against Fornova in Bankruptcy Court. CBI was disputing Fornova's claim that it was owed $500,000 plus accrued interest relating to a convertible note that was originated in 2007. CBI was seeking to have the claim disallowed in its entirety or, in the alternative, reclassified as an equity investment. In October 2012, CBI's claim against Fornova was approved by the Bankruptcy Court. Fornova's claim was disallowed in its entirety. Effective September 30, 2012, principal and accrued interest in the amount of $666,667 was written off and a gain on extinguishment of debt was recognized.

7. **Property and Equipment:**

Property and Equipment relating to CBI consisted of the following:

	December 31, 2013	December 31, 2012
Furniture, fixtures, office and computer equipment	$—	$ 53,575
Other	—	9,077
	$—	$ 62,652
Less accumulated depreciation	—	(62,652)
	$—	$ —

There was no depreciation expense for the years ended December 31, 2013 and 2012.

8. **Other Assets:**

As of December 31, 2012, other current assets include $75,000 relating to cash held in escrow by the Company's bankruptcy attorneys. These funds were used to pay legal fees as approved by the Bankruptcy Court.

9. **Income Taxes:**

The difference between expected income tax benefits and income tax benefits recorded in the financial statements is explained below:

	December 31, 2013	December 31, 2012
Income taxes (benefit) computed at statutory rate	$(627,319)	$ —
State income tax benefit, net	(63,688)	(347)
Change in valuation allowance	691,007	347
	$ —	$ —

The significant components of deferred income tax assets and liabilities consist of the following:

Deferred tax assets (liabilities)	December 31, 2013	December 31, 2012
In-process research and development	$ 346,801	$ —
Net operating loss carry forward	407,398	15,994,583
R&D credit	2,584	52,600
	756,783	16,047,183
Less: valuation allowance	(756,783)	(16,047,183)
	$ —	$ —

**HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012**

9. Income Taxes (continued):

In accordance with GAAP, it is required that a deferred tax asset be reduced by a valuation allowance if, based on the weight of available evidence it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. The valuation allowance should be sufficient to reduce the deferred tax asset to the amount which is more likely than not to be realized. As a result, the Company recorded a valuation allowance with respect to all of the Company's deferred tax assets.

The Company has a federal net operating loss ("NOLs") of approximately $1.1 million as of December 31, 2013. Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation", as defined, there are annual limitations on the amount of the NOLs and other deductions which are available to the Company. The portion of the NOLs incurred prior to August 12, 2013 is subject to this limitation. As such, the use of these NOLs to offset taxable income is limited to approximately $35,000 per year and the Company has written off the deferred tax assets associated with the NOLs limited due to the ownership change that occurred on August 12, 2013. The Company's State NOLS are approximately $1.1 million as of December 31, 2013. These loss carryforwards expire principally beginning in 2018 for federal and state purposes.

10. Chapter 11 Information:

During the year ended December 31, 2013, the Company settled all pre-petition claims associated with the bankruptcy in cash and Common Stock. The Company paid $357,265 in cash and $152,000 in Common Stock to settle the claims. The Common Stock was valued using the 30 day average of the Company's stock price. The $166,676 difference between pre-petition liabilities and the settled amount was recognized as gain on reorganization in the condensed statement of operations for the year ended December 31, 2013. During the year ended December 31, 2012, the Company sought to have a claim relating to a 2008 convertible promissory note disallowed. In October 2012, the claim was disallowed by the Bankruptcy Court. Consequently, principal and interest of approximately $500,000 and $166,667, respectively, were written off effective September 30, 2012. This write-off resulted in a gain on extinguishment of debt of $666,667. Other realized gains for 2012 were approximately $80,000 and resulted from changes in management's estimates regarding the expected settlement amounts of liabilities subject to compromise.

11. Stockholders' Deficit:

Employee Stock Plans

A 2002 Stock Incentive Plan was adopted by the Board of Directors and approved by the shareholders of CBI. However, all options were canceled on July 16, 2013, which was 90 days subsequent to the effective date of the emergence from bankruptcy.

A 2007 Stock Incentive Plan was adopted by the Board of Directors and approved by the shareholders of CBI. However, all options were canceled on July 16, 2013, which was 90 days subsequent to the effective date of the emergence from bankruptcy.

A 2009 Stock Incentive Plan was adopted by the Board of Directors and approved by the shareholders of CBI. There are no options outstanding under this plan.

Going forward, incentive awards may be in the form of stock options, restricted stock, restricted stock units and performance and other awards. In the case of incentive stock options, the exercise price will not be less than 100% of the fair market value of shares covered at the time of the grant, or 110% for incentive stock options granted to persons who own more than 10% of the Company's voting stock. Options granted will generally vest over a three-year period from the date of grant and will be exercisable for ten years, except that the term may not exceed five years for incentive stock options granted to persons who own more than 10% of the Company's outstanding common stock.

Stock-based compensation expense will be determined based on the fair value of the stock-based awards and recognized over the vesting period. No stock-based compensation expense related to employee stock options was recognized for the year ended December 31, 2013 or 2012. As of December 31, 2013 there was no unamortized stock-based compensation cost related to non-vested stock awards, as all such instruments were canceled upon emergence from bankruptcy. During the year ended December 31, 2013, no stock options were granted, exercised or forfeited.

HEDGEPATH P HARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2013 AND 2012

11. Stockholders' Deficit (continued):

Stock option activity for the years ended December 31, 2013 and 2012 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2012	245,443	$ 3.02	
Granted in 2012	—	—	
Exercised	—	—	
Outstanding at December 31, 2012	245,443	$ 3.02	$ —
Granted in 2013	—	—	
Exercised	—	—	
Canceled	(245,443)	3.02	
Outstanding at December 31, 2013	—	$ —	$ —

Issuance of Restricted Stock

In April 2013, restricted shares were issued to CBI's CEO, one CBI board member and one former CBI officer for a portion of their approved claims. The number of shares issued, which totaled 3,328,467, was determined by using a per share price equal to the average of the 30 day closing price of Common Stock and was valued at $152,000.

In September 2012, bonuses, in the form of restricted stock, were issued to a then current CBI employee. Total shares issued were 250,000. The market value of these shares was approximately $5,000.

In December 2010, the Board of Directors approved a resolution allowing former officers of the Company to receive restricted stock in lieu of cash compensation. In August 2012, restricted shares issued to the Company's CEO under this arrangement were 2,025,000. The market value of these shares was approximately $32,000. In September 2012, restricted shares issued to two independent directors under this arrangement were 625,000. The market value of these shares was approximately $13,000.

Warrants

In connection with a 2007 PIPE financing, CBI issued Class A warrants to purchase 975,000 shares of common stock at an exercise price of $2.85 per share that had an expiration date of May 2013. On March 20, 2013, CBI filed a motion to cancel all outstanding warrants under the terms of the Bankruptcy Code. This motion was approved and entered by the Bankruptcy Court in April 2013. As such, there are no warrants outstanding at December 31, 2013.

12. Related party transactions:

On August 1, 2013, the Company formalized amounts due to two former employees and a former director of CBI by issuing three non-interest bearing promissory notes. The two employee notes totaling approximately $62,000 were due on November 1, 2013. Interest will accrue at 18% per annum on any unpaid principal upon default. As of the date of this report, the Company is in default on the aforementioned notes. The Company is now accruing interest in accordance with the specified terms.

On January 31, 2014, the Company extended the two former employee notes. The amendments include additional principal of approximately $9,000 and are due on March 31, 2014.

The former director note of approximately $6,000 is due the later of five days following the date on which the Company has raised $1 million, or November 1, 2013. Default interest accrues at a rate of 5% per annum. Both the employee and director note amounts, including accrued interest, are included in notes payable, related party, in the accompanying balance sheet as of December 31, 2013.

As part of the short-form reincorporation merger with HPPI, certain expenses have been incurred for officer salary, travel, legal and patent expense. These expenses, totaling $366,130, were paid by Hedgepath, LLC on behalf of the newly formed HPPI and are included in due to related party in the accompanying balance sheet as of December 31, 2013. Subsequent to December 31, 3013, working capital advances as of the date of this report from Hedgepath, LLC approximate $100,000, and have been used for officer and employee salaries, legal and professional fees.

Table of Contents

HEDGEPATH PHARM ACEUTICAL S, INC.
CONDENSED BALANCE SHEETS
AS OF JUNE 30, 2014 AND DECEMBER 31, 2013

	June 30, 2014 (Unaudited)	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 271,226	$ 217
Deferred stock issuance costs	—	10,000
Other current assets	29,291	—
Total current assets	300,517	10,217
Total assets	$ 300,517	$ 10,217
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 280,172	$ 287,072
Notes payable	102,420	68,428
Accrued payroll liabilities	16,296	—
Accrued interest	2,483	1,923
Other liabilities	52,500	52,500
Due to related party	—	366,130
Total current liabilities	453,871	776,053
Commitments and contingencies (note 7)	—	—
Stockholders' deficit:		
Series A Preferred Stock, $0.0001 par value; 500,000 shares authorized; 500,000 and 170,001 shares issued and outstanding in 2014 and 2013, respectively	50	17
Undesignated Preferred Stock, $0.0001 par value; 9,500,000 shares authorized; no shares issued or outstanding.	—	—
Common Stock, $0.0001 par value; 340,000,000 shares authorized; 41,419,198 and 18,888,971 shares issued and outstanding in 2014 and 2013, respectively	4,142	1,889
Additional paid-in capital	31,527,255	27,479,913
Common stock subscription receivable	(1,100,000)	—
Accumulated deficit	(30,584,801)	(28,247,655)
Total stockholders' deficit	(153,354)	(765,836)
Total liabilities and stockholders' deficit	$ 300,517	$ 10,217

See notes to condensed financial statements

HEDGEPATH PHARMACEU TICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2014 AND 2013
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Revenues:				
Total Revenues:	—	—	—	—
Expenses:				
Chapter 11 expenses	—	117,324	—	117,324
Research and development expenses	1,930,482	—	1,955,807	—
General and administrative	185,182	286,256	346,787	376,800
Total Expenses:	2,115,664	403,580	2,302,594	494,124
Loss from operations	(2,115,664)	(403,580)	(2,302,594)	(494,124)
Interest expense	(24,994)	—	(34,552)	—
Gain on reorganization	—	166,676	—	166,676
Other expense	—	(30,000)	—	—
Net loss	$ (2,140,658)	$ (266,904)	$ (2,337,146)	$ (327,448)
Basic and diluted loss per share	$ (0.10)	$ (0.01)	$ (0.12)	$ (0.02)
Weighted average common stock shares outstanding	20,622,065	18,376,899	19,760,306	16,976,482

See notes to condensed financial statements

HEDGEPATH PHARMACEUTICA LS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' DEFICIT
FOR THE SIX MONTHS ENDED JUNE 30, 2014
(Unaudited)

	Preferred Stock Series A		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Common Stock Subscription Receivable	Accumulated Deficit	Total Stockholders' Deficit
Balances, January 1, 2014	170,001	$ 17	18,888,971	$ 1,889	$27,479,913	$ —	$(28,247,655)	$ (765,836)
Issuance of preferred and common stock for debt forgiveness	71,636	7	2,530,227	253	189,508	—	—	189,768
Sale of common stock to related party	—	—	20,000,000	2,000	1,498,000	(1,250,000)	—	250,000
Issuance of warrants for debt forgiveness	—	—	—	—	450,000	—	—	450,000
Issuance of common stock warrants in acquisition of research and development license agreement	—	—	—	—	619,134	—	—	619,134
Issuance of preferred stock in acquisition of research and development license agreement	258,363	26	—	—	1,290,700	—	—	1,290,726
Collection of stock subscription receivable						150,000		150,000
Net loss	—	—	—	—	—	—	(2,337,146)	(2,337,146)
Balances, June 30, 2014	500,000	$ 50	41,419,198	$ 4,142	$31,527,255	$(1,100,000)	$(30,584,801)	$ (153,354)

See notes to condensed financial statements

Table of Contents

HEDGEPATH PHARMAC EUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
FOR THE SIX MONTHS ENDED JUNE 30, 2014 AND 2013
(Unaudited)

	Six months Ended June 30, 2014	2013
Operating activities:		
Net loss	$(2,337,146)	$(327,448)
Adjustments to reconcile net loss to net cash flows from operating activities:		
In-process research and development purchased with the issuance of preferred stock and common stock warrants	1,909,860	—
Non-cash interest expense	24,666	—
Changes in assets and liabilities:		
Prepaid expense and other current assets	(19,291)	78,371
Accounts payable and other current liabilities	19,282	(152,836)
Net cash flows from operating activities before reorganization items	(402,629)	(401,913)
Reorganization items:		
Gain on reorganization	—	(166,676)
Decrease in liabilities subject to compromise	—	(357,265)
Net cash flows from operating activities	(402,629)	(925,854)
Financing activities:		
Proceeds from related party advances	273,638	69,264
Proceeds from sale of common stock, related party	400,000	—
Net cash flows from financing activities	673,638	69,264
Net change in cash and cash equivalents	271,009	(856,590)
Cash and cash equivalents at beginning of period	217	857,702
Cash and cash equivalents at end of period	$ 271,226	$ 1,112
Supplemental disclosure of non-cash financing activity:		
Stock payments to officers and directors (liabilities subject to compromise) in lieu of cash payments under the Bankruptcy Plan	$ —	$ 152,000
Issuance of stock in debt forgiveness transaction	$ 189,768	$ —
Issuance of warrants in debt forgiveness transaction	$ 450,000	$ —
Issuance of common stock for common stock subscription receivable	$ 1,100,000	$ —

See notes to condensed financial statements

HEDGEPATH PHARMACEUTI CALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE SIX MONTHS ENDED JUNE 30, 2014 AND 2013
(Unaudited)

1. Corporate overview:

Overview

The accompanying unaudited condensed financial statements of HedgePath Pharmaceuticals, Inc., a Delaware corporation (the "Company", "HPPI", "we", "us" or similar terminology) as successor to Commonwealth Biotechnologies, Inc., a Virginia corporation ("CBI"), have been prepared by the Company without audit. In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present fairly the financial position, results of operations and cash flows at June 30, 2014, and for all periods presented, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to the Securities and Exchange Commission ("SEC") rules and regulations. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2013, which are included in the Company's 2013 Annual Report on Form 10-K, filed with the SEC on April 15, 2014 (the "2013 Annual Report"). The accompanying condensed balance sheet at December 31, 2013 has been derived from the audited financial statements at that date, but does not include all information and footnotes required by GAAP for complete financial statements.

As used herein, the term "Common Stock" means the Company's common stock, $0.0001 par value per share.

The results of operations for the six month period ended June 30, 2014 are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year. Readers of this Quarterly Report are strongly encouraged to review the risk factors relating to the Company which are set forth in the 2013 Annual Report.

The accompanying financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities of the Company in the normal course of business. If the Company is unable to raise required funding to continue to pursue its business plan, it may have to cease operations. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Nature of the Business and Background

The Company is a clinical stage biopharmaceutical company that is seeking to discover, develop and commercialize innovative therapeutics for patients with certain cancers. The Company's preliminary focus is on the development of therapies for skin, prostate and lung cancers in the U.S. market, with the first indication targeting the treatment of basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome (also known as Gorlin Syndrome). The Company believes that the dosing of oral capsules of SUBA-Itraconazole can affect the Hedgehog signaling pathway, a major regulator of many fundamental cellular processes, which, in turn, can impact the development and growth of cancers such as basal cell carcinoma.

Itraconazole is FDA approved for and extensively used to treat fungal infections and has an extensive history of safe and effective use in humans. The Company has developed, optioned and licensed intellectual property and know-how related to the treatment of cancer patients using itraconazole and has applied for patents to cover the Company's inventions.

On January 20, 2011, CBI (which had operated as a biotechnology company) filed a voluntary petition captioned *In re Commonwealth Biotechnologies, Inc., Case No. 11-30381-KRH* in the United States Bankruptcy Court for the Eastern District of Virginia (the "Bankruptcy Court") seeking relief under the provisions of Chapter 11 of Title 11 of the United States Code. On August 12, 2013, in furtherance of CBI's plan of reorganization approved by the Bankruptcy Court, CBI effected a "short-form" reincorporation merger with HPPI, a newly created and wholly owned Delaware subsidiary of CBI, pursuant to which CBI merged with and into HPPI, with HPPI surviving the merger and with the effect of CBI becoming reincorporated as a Delaware corporation and changing its corporate name. Each outstanding share of CBI was converted into one share of HPPI. HPPI's Certificate of Incorporation (and thus the Certificate of Incorporation of the surviving company) authorizes the issuance of up to 340,000,000 shares of Common Stock, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

On August 13, 2013, the Company entered into a Contribution Agreement, dated as of August 13, 2013 (the "Contribution Agreement"), by and between the Company and Hedgepath, LLC (a related party) ("HPLLC") pursuant to which, in exchange for the right to receive 170,001 shares of the Company's newly created Series A Convertible Preferred Stock (the "Series A Preferred

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE SIX MONTHS ENDED JUNE 30, 2014 AND 2013
(Unaudited)

1. Corporate overview (continued):

Stock"), representing 90% of the fully diluted voting securities of the Company as of the date of issuance (or 170,000,739 shares of Common Stock on an as converted basis), HPLLC contributed and/or assigned various assets and contract rights to the Company associated with the itraconazole cancer therapy business presently conducted by the Company. All issued Series A Preferred Stock will convert into 170,000,739 shares of Common Stock. Therefore, issuances of Series A Preferred Stock subsequent to this initial issuance will reduce the conversion rate and result in fewer shares of Common Stock upon conversion of the 170,001 shares of Preferred Stock issued in this transaction.

Supply and License Agreement

On September 3, 2013, the Company entered into an exclusive Supply and License Agreement (the "Supply and License Agreement") with Mayne Pharma International Pty Ltd., a company incorporated in Australia ("MPI"), pursuant to which MPI agreed to: (i) supply the Company with its patented formulation of the drug itraconazole, known as SUBA™-Itraconazole, in a particular dose formulation (the "Product") for the treatment of human patients with cancer via oral administration (the "Field") (with the initial areas of investigation being skin, lung and prostate cancer) in the United States (the "Territory"), (ii) provide the Company with an exclusive license to use and develop the intellectual property related to the Product in the Field and in the Territory and (iii) participate in a joint development committee with the Company ("JDC") to clinically develop the Product in the Field and in the Territory. The Company will pursue the development of the Product for treatment of a variety of cancers with a focus on clinical development, seeking regulatory approvals and, if regulatory approval is obtained, marketing in the United States.

Subject to earlier termination if certain conditions ("Conditions") were not met (which Conditions were eliminated as described further below), the term of the Supply and License Agreement shall last until the later of: (i) 10 years from the target launch date of the Product for the treatment of human patients with cancer via oral administration or (ii) the date on which all issued patents of MPI or any of its affiliates referred to in the Supply and License Agreement have lapsed or expired. The Company entered into Amendment No. 1 and Amendment No. 2 to the Supply and License Agreement (the "Amended Supply and License Agreement") with MPI to extend the date by which the Conditions were to be met from December 16, 2013.

On June 24, 2014, the Company and Mayne Pharma Ventures Pty Ltd ("Mayne Pharma"), an Australian company and assignee of MPI's rights, along with Nicholas J. Virca, the Company's President and Chief Executive Officer ("Virca"), Frank O'Donnell, Jr., M.D., the Company's Executive Chairman ("O'Donnell") and HPLLC, consummated a series of related transactions to fulfill the Conditions in a manner mutually acceptable to the Company and Mayne Pharma. In connection therewith, the Company and Mayne Pharma entered into an Amended and Restated Supply and License Agreement as of June 24, 2014 (the "Amended and Restated Supply and License Agreement") principally to eliminate the Conditions and related early termination rights of Mayne Pharma.

Mayne Pharma Securities Purchase Agreement

On June 24, 2014, the Company and Mayne Pharma entered into the Mayne Purchase Agreement (the "Mayne Purchase Agreement"). Pursuant to the Mayne Purchase Agreement, the Company (i) issued 258,363.280 shares of Series A Preferred Stock (the "Mayne Series A Shares") and (ii) issued, upon closing of a Purchase Agreement, dated June 24, 2014 (as described further below, the "HPLLC Purchase Agreement") by and between the Company and HPLLC, a warrant to purchase 10,250,569 shares of Common Stock (the "Mayne Make-Up Warrant"). The Mayne Series A Shares will convert into 87,843,897 shares of Common Stock in August 2014 pursuant to the terms of the Equity Holders Agreement (discussed below) and in accordance with the Amended and Restated Certificate of Designation of Series A Preferred Stock (the "Certificate of Designation"). The Mayne Make-Up Warrant has an exercise price of $0.0878 per share and may be exercised at any time, from time to time, by Mayne Pharma prior to the expiration on June 24, 2019. In conjunction with the execution of the Mayne Purchase Agreement, the Company has expensed, as in-process research and development costs, approximately $1.9 million. The value of the issued stock was calculated by taking approximately 42% of the market capitalization on the date the agreement was entered into to reflect the 42% ownership exchanged for entering into the agreement. The value of the warrant was calculated by using the Black-Scholes valuation model that uses assumptions for expected volatility (104.9%), expected dividends (none), expected term (5 years), and risk-free interest rate (1.7%). Expected volatilities are based on historical volatilities of peer companies. The risk-free rate is based upon the U.S. Treasury yield curve in effect at the time of the grant for the period of the expected term.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE SIX MONTHS ENDED JUNE 30, 2014 AND 2013
(Unaudited)

1. Corporate overview (continued):

Equity Holders Agreement

On June 24, 2014, in fulfillment of one of the Conditions of the Supply and License Agreement, and as a condition of the Mayne Purchase Agreement and in consideration for Mayne Pharma not exercising its termination right, the Company, Mayne Pharma, HPLLC, O'Donnell and Virca (together, the "Equity Holder Parties") entered into an Equity Holders Agreement (the "Equity Holders Agreement"). The Equity Holders Agreement governs the rights and obligations of each of the parties as they pertain to the Company's securities and to the present and future governance of the Company. Pursuant to the Equity Holders Agreement:

- Mayne Pharma and HPLLC each agreed not to offer, pledge, sell, contract to sell, swap or enter into any other transfer arrangement any of their Company securities until June 24, 2015 (the "Lock-Up Period") without prior written consent of the other Equity Holder Parties, except for in limited circumstances as described in the Equity Holders Agreement;
- Mayne Pharma and HPLLC each agreed that on August 14, 2014 (or within 2 business days thereafter) each will convert all of its Series A Preferred Stock into shares of Common Stock at a rate of 1 for 340 shares of Common Stock. All 500,000 shares of Series A Preferred Stock will convert into 170,000,739 shares of Common Stock of the Company;
- Mayne Pharma, HPLLC, Virca and O'Donnell each agreed that during the Lock-Up Period none of them will own greater than 49.5% of the Common Stock of the Company on a fully-diluted basis (such ownership to include individual and affiliate ownership) and that after the Lock-Up Period and until June 24, 2019, each of the Equity Holder Parties will provide written notice to each of the other Equity Holder Parties if their ownership (together with affiliates) exceeds, or is going to exceed, 49.5%;
- Mayne Pharma and its affiliates (the "Mayne Pharma Group") have been granted a right of first refusal to purchase a pro rata share of any new securities issued by the Company, such pro rata share to be determined based upon the number of shares of Common Stock held by Mayne Pharma Group on a fully diluted basis as compared to the number of shares of Common Stock outstanding immediately prior to the offering of the new securities on a fully diluted basis;
- Mayne Pharma has been granted the right until June 24, 2016 to introduce accredited investors to the Company to participate in a private offering of the Company's securities (with some exceptions as described in the Equity Holders Agreement). In the event that the Company contemplates a private offering of its securities, such accredited investors introduced by Mayne Pharma to have the right to participate in up to 50% of the private offering;
- Mayne Pharma has the right to immediately designate one director to the Company's Board of Directors (the "Board") and to designate a second director if the size of the Board is increased to seven directors until the earlier to occur of: (i) the date that the Amended and Restated Supply and License Agreement is terminated or expires, or (ii) the date on which the Mayne Pharma Group ceases to own ten percent (10%) or more of the issued and outstanding Common Stock on a fully diluted basis (the "Voting Rights Termination Date");
- The Equity Holder Parties agree that if HPLLC fails to satisfy certain performance goals, defaults under the HPLLC Note (as defined and further discussed below), or breaches any provisions of the HPLLC Note then the Company has the right to declare that 17,647 shares of Series A Preferred Stock (or the Common Stock equivalent upon conversion thereof) be forfeited and Mayne Pharma has the right to purchase such forfeited shares; and
- The Equity Holder Parties agree that if HPLLC defaults under the HPLLC Note or breaches any provisions of the HPLLC Note, then Mayne Pharma has the right to demand the resignation of O'Donnell.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE SIX MONTHS ENDED JUNE 30, 2014 AND 2013
(Unaudited)

1. Corporate overview (continued):

In addition to the foregoing, the Equity Holder Parties also agreed that the Company would seek to meet certain goals for the commercialization of the Product (the "Commercialization Goals") and certain funding goals for the Company (the "Funding Goals"). In the event that the Company fails to achieve the Commercialization Goals or the Funding Goals, Mayne Pharma has the right to demand the resignation of O'Donnell and/or Virca from their positions with the Company. In the event that O'Donnell or Virca do not submit their resignations in a timely manner, Mayne Pharma can terminate the Amended and Restated Supply and License Agreement. Additionally, if the Commercialization Goals are not achieved, the Company has the right to declare that HPLLC forfeit 17,647 shares of Series A Preferred Stock (or the Common Stock equivalent upon conversion thereof).

If O'Donnell or Virca are required to resign pursuant to the Equity Holders Agreement, then, notwithstanding the Employment Agreement between the Company and Virca or the Executive Chairman Agreement between the Company and O'Donnell, no severance, compensation, consideration or other payment will be due or payable in connection therewith and O'Donnell or Virca, as the case may be, will forfeit all then unvested options, warrants, restricted stock units, or other right to acquire Common Stock (or securities convertible into Common Stock) and will waive any claim to severance pay. Furthermore, upon such resignation or termination, Mayne Pharma will have the right to purchase by written notice to O'Donnell or Virca, as the case may be, all Company securities owned by O'Donnell or Virca, including vested options, vested warrants, vested restricted stock units and the like individually held by O'Donnell and/or Virca or otherwise transferred by either of them, as the case may be, at the fair market value (as such term is defined in the Equity Holders Agreement) as of the date of such resignation or termination.

The Equity Holders Agreement terminates if (i) the Company receives an adjudication of bankruptcy, the Company executes an assignment for the benefit of creditors, a receiver is appointed for the Company or the Company is voluntarily or involuntarily dissolved or (ii) the Company, HPLLC and Mayne Pharma expressly agree in writing. Additionally, certain limited provisions of the Equity Holders Agreement terminate at such time as the Mayne Pharma Group collectively owns less than ten percent (10%) of the Common Stock on a fully diluted basis.

Related Party Debt Forgiveness Agreement

Following the Company's emergence from bankruptcy in August 2013, certain expenses had been incurred for officer salary, travel, legal and patent expenses. These expenses, totaling $639,768, were paid by HPLLC on behalf of the Company. This debt was forgiven pursuant to a Debt Forgiveness Agreement, dated June 24, 2014 (the "Debt Forgiveness Agreement"), which was entered into by the Company and HPLLC as a condition of closing of the Mayne Purchase Agreement and was accounted for as a capital transaction due to the related party nature of the agreement. Pursuant to the Debt Forgiveness Agreement, HPLLC waived, canceled and forgave payment from the Company of the aforementioned $639,768 of indebtedness previously advanced by HPLLC to the Company in exchange for 2,530,227 shares of Common Stock, 71,636 shares of Series A Preferred Stock (the "Debt Forgiveness Series A Shares") and a warrant (the "Debt Forgiveness Warrant") to purchase 10,250,569 shares of Common Stock. The Debt Forgiveness Series A Shares together with Series A Preferred Shares previously issued to HPLLC will convert into 82,156,842 shares of Common Stock in August 2014 pursuant to the terms of the Equity Holders Agreement and in accordance the Certificate of Designation. The Debt Forgiveness Warrant may be exercised by HPLLC at an exercise price of $0.0878 per share at any time, from time to time, prior to the expiration of the Debt Forgiveness Warrant on June 24, 2019.

HPLLC Purchase Agreement

Also on June 24, 2014, the Company and HPLLC entered into the HPLLC Purchase Agreement, pursuant to which the Company sold HPLLC 20,000,000 shares of Common Stock at a purchase price of $0.075 per share for an aggregate purchase price of $1,500,000. HPLLC funded $400,000 of the purchase price prior to June 30, 2014. The remaining $1,100,000 will be funded in monthly installments through December 31, 2014 pursuant to a promissory note (the "HPLLC Note") issued by HPLLC to the Company on June 24, 2014. Funds received under this transaction are being used by the Company for research and development as well as for general and administrative expenses (note 4).

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE SIX MONTHS ENDED JUNE 30, 2014 AND 2013
(Unaudited)

2. Liquidity and management's plans:

The Company requires additional financing for its research and development, commercialization and distribution efforts and its working capital and intends to finance these activities primarily through:

- public and private financings and, potentially, from strategic transactions;
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of its products for which the Company would expect to receive upfront milestone and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where the Company would receive funding based on out-licensing its product; and
- seeking government or private foundation grants which would be awarded to the Company to further develop its current and future anti-cancer therapies.

However, there can be no assurance that any of these plans will be implemented on commercially reasonable terms, if at all.

There is substantial doubt about the Company's ability to continue as a going concern. The Company's current independent auditors have included a paragraph emphasizing "going concern" uncertainty in their report on the 2013 financial statements. The financial statements included herein do not include any adjustments relating to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should the Company be unable to continue as a going concern.

The Company had cash and cash equivalents of $271,226 as of June 30, 2014.

3. Summary of Significant Accounting Policies:

Estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

Revenue Recognition

The Company currently has no ongoing source of revenues. Any miscellaneous income is recognized when earned by the Company.

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. At times, the Company may maintain cash balances in excess of Federal Deposit Insurance Corporation insured amounts.

Research and Development Expenses

Research and development costs are expensed in the period in which they are incurred and include the expenses paid to third parties who conduct research and development activities on behalf of the Company.

Recent accounting pronouncements:

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update 2014-09, "Revenue from Contracts with Customers," which supersedes the revenue recognition requirements of Accounting Standards Codification ("ASC") Topic 605, "Revenue Recognition" and most industry-specific guidance on revenue recognition throughout the ASC. The new standard is principles-based and provides a five step model to determine when and how revenue is recognized. The core principle of the new standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The new standard also

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE SIX MONTHS ENDED JUNE 30, 2014 AND 2013
(Unaudited)

3. Summary of Significant Accounting Policies (continued):

requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. The new standard will be effective for the Company in the first quarter of the year ending December 31, 2017 and can be applied either retrospectively to all periods presented or as a cumulative-effect adjustment as of the date of adoption. Early adoption is not permitted. The Company will evaluate the impact of adoption of the new standard on its financial statements upon commencement of revenue generating activities.

Accounting for Enterprises in Reorganization

Financial Accounting Standards Board (" FASB") Accounting Standards Codification ("ASC") Topic 852—*Reorganizations* ("ASC Topic 852"), which is applicable to companies in Chapter 11, generally does not change the manner in which financial statements are prepared. However, it does require that the financial statements for periods subsequent to the filing of the Chapter 11 petition distinguish transactions and events that are directly associated with the reorganization from the ongoing operations of the business. Revenues, expenses, realized gains and losses, and provisions for losses that can be directly associated with the reorganization and restructuring of the business must be reported separately as reorganization items in the statements of operations beginning in the quarter ending March 31, 2011. The balance sheet must distinguish prepetition liabilities subject to compromise from both those prepetition liabilities that are not subject to compromise and from post-petition liabilities. Liabilities that may be affected by a plan of reorganization must be reported at the amounts expected to be allowed by the applicable bankruptcy court, even if they may be settled for lesser amounts. In addition, cash flows from reorganization items must be disclosed separately in the statement of cash flows. The Company became subject to ASC Topic 852 effective on January 20, 2011, and segregated those items as outlined above for all reporting periods after such date. The Company officially emerged from bankruptcy on April 17, 2013, followed by the reincorporation merger and contribution of assets by HPLLC, which satisfied the final condition to effectiveness of the Company's reorganization plan as detailed in Note 1. Accordingly, all pre-petition liabilities had been settled as of December 31, 2013, and there are no further reorganization items requiring recognition in the 2014 statement of operation.

Income Taxes

Deferred tax assets and liabilities are recognized for future tax consequences attributed to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and are measured using enacted tax rates that are expected to apply to the differences in the periods that they are expected to reverse. Management has evaluated the guidance relating to accounting for uncertainty in income taxes and has determined that the Company had no uncertain income tax positions that could have a significant effect on the consolidated financial statements for the six months ended June 30, 2014 or 2013.

Supply and License Agreement:

Upon entering into the Amended and Restated Supply and License Agreement with Mayne Pharma, the Company issued 258,363 shares of Series A Preferred Stock and a warrant to purchase 10,250,569 shares of Common Stock to Mayne Pharma. The fair value of the issued Preferred shares and warrants has been accounted for as in-process research and development totaling approximately $1.9 million and is included in research and development expense for the quarter ended June 30, 2014.

4. Notes Receivable:

Pursuant to the HPLLC Note (as described in note 1), commencing on June 30, 2014 and ending on December 31, 2014, HPLLC must make monthly payments to the Company in accordance with the terms and conditions of that note. The Company has the right, in its sole discretion, to request an advance payment of part or all of the principal of the HPLLC Note from HPLLC. The HPLLC Note bears no interest except upon an event of default in which case interest accrues at 18% per annum. In the event that HPLLC defaults on part or all of the HPLLC Note, the Company has the right to declare by written notice that HPLLC forfeit some or all of the 20,000,000 HPLLC Common Stock shares sold in consideration for the note as well as 17,647 shares of Series A Preferred Stock (or the Common Stock equivalent upon conversion thereof) held by HPLLC. The balance due under the HPLLC Note as of June 30, 2014 was $1,100,000 and is classified as a Common Stock Subscription Receivable in the accompanying 2014 condensed balance sheet.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE SIX MONTHS ENDED JUNE 30, 2014 AND 2013
(Unaudited)

5. Notes Payable:

On August 1, 2013, the Company formalized amounts due to two former employees and a former director of CBI by issuing three non-interest bearing promissory notes. The two employee notes totaling approximately $62,000 were due on November 1, 2013. Interest began accruing at 18% per annum on the unpaid principal on November 1, 2013, in accordance with the specified terms. On January 31, 2014, the Company extended the two former employee notes to March 31, 2014 while adding accrued interest through January 31, 2014 and an additional $3,000 to the principal balance of each. Additional extensions were entered into in May 2014 to extend the maturity to July 12, 2014, which includes additional principal of approximately $9,000 each along with accrued and unpaid interest through May 13, 2014. On July 10, 2014, a partial payment of $57,000 was made by the Company and the maturity was extended to December 31, 2014, with an interest rate of 9% per annum effective July 10, 2014.

The former director non-interest bearing note of approximately $6,000 was due the later of five days following the date on which the Company has raised $1 million, or November 1, 2013. Interest began accruing at a rate of 5% per annum on November 1, 2013 in accordance with the specified terms. The former director note and the related accrued and unpaid interest were paid in full on July 2, 2014.

6. Stockholders' Equity:

Employee Stock Plans

Subsequent to June 30, 2014, a 2014 Equity Incentive Plan ("EIP") was adopted by the Company's Board of Directors and is currently pending approval by the stockholders of the Company. The 2014 EIP authorizes the issuance of up to 32,583,475 shares of Company common stock. In July 2014, 15,041,738 restricted stock units ("RSUs") were granted (subject to approval of the EIP by the Company's stockholders) to the Company's Chief Executive Officer, Nicholas J. Virca, and shall vest upon the earlier to occur of (i) September 3, 2016 or (ii) the acceptance by the FDA of a New Drug Application ("NDA") by the Company for any Company product candidate with a cancer indication utilizing the Company's licensed SUBA-itraconazole technology, provided that Mr. Virca is actively employed by the Company on the earlier of such date. An additional 1.5 million RSUs were issued to various Board members and officers with the same vesting schedule and subject to the same stockholder approval requirement.

Going forward, incentive awards may be in the form of stock options, restricted stock, restricted stock units and performance and other awards. In the case of incentive stock options, the exercise price will not be less than 100% of the fair market value of shares covered at the time of the grant, or 110% for incentive stock options granted to persons who own more than 10% of the Company's voting stock. Options granted will generally vest over a three-year period from the date of grant and will be exercisable for ten years, except that the term may not exceed five years for incentive stock options granted to persons who own more than 10% of the Company's outstanding common stock.

Stock-based compensation expense will be determined based on the fair value of the stock-based awards and recognized over the vesting period. No stock-based compensation expense related to employee stock options was recognized for the six months ended June 30, 2014 or 2013. As of June 30, 2014 there was no unamortized stock-based compensation cost related to non-vested stock awards, as all such instruments were canceled upon emergence from bankruptcy. During the six months ended June 30, 2014, no stock options were granted, exercised or forfeited.

Issuance of Restricted Stock

In April 2013, restricted shares were issued to CBI's CEO, one CBI board member and one former CBI officer for a portion of their approved claims. The number of shares issued, which totaled 3,328,467, was determined by using a per share price equal to the average of the 30 day closing price of Common Stock and was valued at $152,000.

Issuance of Preferred and Common Stock

See note 1 for discussion of Series A Preferred Stock issued to Mayne Pharma for purchased in-process research and development.

See note 1 for discussion of Series A Preferred Stock issued for related party debt forgiveness.

See note 1 for discussion of Common Stock issued for Common Stock subscription.

HEDGEPATH PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
FOR THE SIX MONTHS ENDED JUNE 30, 2014 AND 2013
(Unaudited)

6. Stockholders' Equity (continued):

Warrants

Pursuant to the Mayne Purchase Agreement (note 1), warrants to purchase 10,250,569 shares of the Company's common stock at $0.0878 was granted to Mayne Pharma. The warrants will expire on June 24, 2019.

Pursuant to the Debt Forgiveness Agreement (note 1) with HPLLC, warrants to purchase 10,250,569 shares of the Company's common stock at $0.0878 was granted to HPLLC. The warrants will expire on June 24, 2019.

7. Legal Proceedings:

Chien Connecticut Case

In October 2012, Andrew Chien ("Chien"), an alleged shareholder of our predecessor, CBI, filed suit in Connecticut state court (later removed to the United States District Court for the District of Connecticut (the "CT District Court")) against CBI, Dr. Richard J. Freer (a director and officer of CBI) ('Freer"), and the law firm LeClairRyan (the "Chien Connecticut Case").

In October 2012, the CT District Court in the Chien Connecticut Case entered an Order dismissing Chien's claims without prejudice on account of CBI's pending Chapter 11 bankruptcy.

Chien filed various motions in response to the CT District Court's decision dismissing the claims asserted against Freer and LeClairRyan, including a motion for reconsideration. On Thursday, May 29, 2014, the presiding judge issued several orders. The CT District Court granted Chien's request that he be allowed to proceed with the fifth and six claims he asserted against CBI in his Complaint, namely (i) a claim for relief entitled "Securities Fraud and Fiduciary Duty Violation against CBI" and (ii) a claim for relief entitled "Fiduciary Duty violation against CBI" (collectively, the "Chien Claims"). A related scheduling order provided that CBI had until June 20, 2014 to answer or otherwise respond to the Complaint. We have retained LeClairRyan to serve as CBI's counsel in the Chien Connecticut Case. On June 20, 2014, LeClairRyan filed on CBI's behalf a motion to dismiss seeking a dismissal with prejudice of the Chien Claims. LeClairRyan also filed on CBI's behalf a motion to stay discovery. On August 5, 2014, the CT District Court granted CBI's motion to stay discovery. The parties are now awaiting a final decision on CBI's motion to dismiss.

The Company strongly refutes as without merit the Plaintiff's claims and will vigorously defend the lawsuit

Chien Virginia Case

In April 2013, Chien filed an adversary proceeding to recover monetary and injunctive relief against CBI and Freer in the United States Bankruptcy Court for the Eastern District of Virginia (the "EDVA Bankruptcy Court"). On June 19, 2013, the EDVA Bankruptcy Court held a hearing on CBI's and Freer's motions to strike and / or dismiss Chien's adversary proceeding Complaint. At the conclusion of the June 19, 2013 hearing the EDVA Bankruptcy Court granted CBI's and Freer's motions to strike and / or dismiss and ordered that Chien's adversary proceeding be dismissed. On July 1, 2013, the EDVA Bankruptcy Court entered a Memorandum Opinion memorializing its decision. Chien perfected an appeal of the EDVA Bankruptcy Court's decision (the "Bankruptcy Appeal") to the United States District Court for the Eastern District of Virginia (the "EDVA District Court"). The parties have fully briefed the Bankruptcy Appeal and are now awaiting a decision from the EDVA District Court.

The Company strongly refutes as without merit the Plaintiff's claims and will vigorously defend the lawsuit

[Table of Contents](#)

You should rely only on the information contained in this document. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information in this document may only be accurate on the date of this document.

Additional risks and uncertainties not presently known or that are currently deemed immaterial may also impair our business operations. The risks and uncertainties described in this document and other risks and uncertainties which we may face in the future will have a greater impact on those who purchase our common stock. These purchasers will purchase our common stock at the market price or at a privately negotiated price and will run the risk of losing their entire investment.

HedgePath Pharmaceuticals, Inc.

SHARES
COMMON STOCK

PROSPECTUS

Placement Agent

H.C. Wainwright & Co., LLC

, 2014

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the expenses in connection with this registration statement. All of such expenses are estimates, other than the filing fees payable to the Securities and Exchange Commission and to FINRA.

Description	*Amount to be Paid*
Filing Fee - Securities and Exchange Commission	$ 672.34
Filing Fee - FINRA	1,283.00
Attorney's fees and expenses	275,000.00*
Accountant's fees and expenses	15,000.00*
Transfer agent's and registrar fees and expenses	5,000.00*
Printing and engraving expenses	15,000.00*
Miscellaneous expenses	5,000.00*
Total	$316,955.34*

* Estimated

ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any threatened, pending or completed actions, suits or proceedings in which such person is made a party by reason of such person being or having been a director, officer, employee or agent of the corporation. Section 145 of the Delaware General Corporation Law also provides that expenses (including attorneys' fees) incurred by a director or officer in defending an action may be paid by a corporation in advance of the final disposition of an action if the director or officer undertakes to repay the advanced amounts if it is determined such person is not entitled to be indemnified by the corporation. The Delaware General Corporation Law provides that Section 145 is not exclusive of other rights to which those seeking indemnification may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise. Our amended and restated bylaws provide that, to the fullest extent permitted by law, we shall indemnify and hold harmless any person who was or is made or is threatened to be made a party or is otherwise involved in any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative by reason of the fact that such person, or the person for whom he is the legally representative, is or was a director or officer of ours, against all liabilities, losses, expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such proceeding.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) for unlawful payments of dividends or unlawful stock repurchases, redemptions or other distributions, or (iv) for any transaction from which the director derived an improper personal benefit.

Our certificate of incorporation provides that we shall, to the maximum extent permitted from time to time under the law of the State of Delaware, indemnify and upon request shall advance expenses to any person who is or was a party or is threatened to be made a party to any threatened, pending or completed action, suit, proceeding or claim, whether civil, criminal, administrative or investigative, by reason of the fact that such person is or was or has agreed to be a director or officer of ours or while a director or officer is or was serving at our request as a director, officer, partner, trustee, employee or agent of any corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorneys' fees and expenses), judgments, fines, penalties and amounts paid in settlement incurred in connection with the investigation, preparation to defend or defense of such action, suit, proceeding or claim; provided, however, that the foregoing shall not require us to indemnify or advance expenses to any person in connection with any action, suit, proceeding or claim initiated by or on behalf of such person or any counterclaim against us initiated by or on behalf of such person. Such indemnification shall not be exclusive of other indemnification rights arising under any by-law, agreement, vote of directors or stockholders or otherwise and shall inure to the benefit of the heirs and legal representatives of such person. Any person seeking indemnification shall be deemed to have met the standard of conduct required for such indemnification unless the contrary shall be established. Any repeal or modification of our certificate of incorporation shall not adversely affect any right or protection of a director or officer of ours with respect to any acts or omissions of such director or officer occurring prior to such repeal or modification.

Our amended and restated bylaws provide we shall, to the fullest extent permitted under the laws of the State of Delaware, as amended and supplemented from time to time, indemnify each person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such party is or was, or has agreed to become, a director or officer of ours, or is or was serving, or has agreed to serve, at our request, as a director, officer or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, including any employee benefit plan, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such party or on such party's behalf in connection with such action, suit or proceeding and any appeal therefrom.

Expenses incurred by such a person in defending a civil or criminal action, suit or proceeding by reason of the fact that such person is or was, or has agreed to become, a director or officer of ours, or is or was serving, or has agreed to serve, at our request, as a director, officer or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, including any employee benefit plan, or by reason of any action alleged to have been taken or omitted in such capacity shall be paid by us in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such person to repay such amount if it shall ultimately be determined that he is not entitled to be indemnified by us as authorized by relevant sections of the Delaware General Corporation Law. Notwithstanding the foregoing, we shall not be required to advance such expenses to a person who is a party to an action, suit or proceeding brought by us and approved by a majority of our Board of Directors that alleges willful misappropriation of corporate assets by such person, disclosure of confidential information in violation of such person's fiduciary or contractual obligations to us or any other willful and deliberate breach in bad faith of such person's duty to us or our stockholders.

We shall not indemnify any such person seeking indemnification in connection with a proceeding (or part thereof) initiated by such person unless the initiation thereof was approved by our Board of Directors.

The indemnification rights provided in our amended and restated bylaws shall not be deemed exclusive of any other rights to which those indemnified may be entitled under any by-law, agreement or vote of stockholders or disinterested directors or otherwise, both as to action in their official capacities and as to action in another capacity while holding such office, continue as to such person who has ceased to be a director or officer, and inure to the benefit of the heirs, executors and administrators of such a person.

If the Delaware General Corporation Law is amended to expand further the indemnification permitted to indemnitees, then we shall indemnify such persons to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

We may, to the extent authorized from time to time by our Board of Directors, grant indemnification rights to other employees or agents of ours or other persons serving us and such rights may be equivalent to, or greater or less than, those set forth in our amended and restated bylaws.

Our obligation to provide indemnification under our amended and restated bylaws shall be offset to the extent of any other source of indemnification or any otherwise applicable insurance coverage under a policy maintained by us or any other person.

To assure indemnification under our amended and restated bylaws of all directors, officers, employees or agents who are determined by us or otherwise to be or to have been “fiduciaries” of any employee benefit plan of ours that may exist from time to time, Section 145 of the Delaware General Corporation Law shall, for the purposes of our amended and restated bylaws, be interpreted as follows: an “other enterprise” shall be deemed to include such an employee benefit plan, including without limitation, any plan of ours that is governed by the Act of Congress entitled “Employee Retirement Income Security Act of 1974,” as amended from time to time; we shall be deemed to have requested a person to serve an employee benefit plan where the performance by such person of his duties to us also imposes duties on, or otherwise involves services by, such person to the plan or participants or beneficiaries of the plan; and excise taxes assessed on a person with respect to an employee benefit plan pursuant to such Act of Congress shall be deemed “fines.”

Our amended and restated bylaws shall be deemed to be a contract between us and each person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that person is or was, or has agreed to become, a director or officer of ours, or is or was serving, or has agreed to serve, at our request, as a director, officer or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, including any employee benefit plan, or by reason of any action alleged to have been taken or omitted in such capacity, at any time while this by-law is in effect, and any repeal or modification thereof shall not affect any rights or obligations then existing with respect to any state of facts then or theretofore existing or any action, suit or proceeding theretofore or thereafter brought based in whole or in part upon any such state of facts.

The indemnification provision of our amended and restated bylaws does not affect directors’ responsibilities under any other laws, such as the federal securities laws or state or federal environmental laws.

We may purchase and maintain insurance on behalf of any person who is or was a director, officer or employee of ours, or is or was serving at our request as a director, officer, employee or agent of another company, partnership, joint venture, trust or other enterprise against liability asserted against him and incurred by him in any such capacity, or arising out of his status as such, whether or not we would have the power to indemnify him against liability under the provisions of this section. We currently maintain such insurance.

The right of any person to be indemnified is subject to our right, in lieu of such indemnity, to settle any such claim, action, suit or proceeding at our expense of by the payment of the amount of such settlement and the costs and expenses incurred in connection therewith.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities (other than the payment of expenses incurred or paid by a director, officer or controlling person in a successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered herewith, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to the court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES

On August 13, 2013, we issued to Hedgepath, LLC, as consideration for the contribution of certain assets as described in that certain contribution agreement, dated August 13, 2013 by and between us and Hedgepath, LLC, an aggregate of 170,000.739 shares of Series A Preferred Stock which have since been converted into 82,156,842 shares of common stock. Such securities were issued in a transaction exempt from the registration requirements under Section 4(a)(2) and/or Regulation D of the Securities Act inasmuch as they were issued to less than ten sophisticated persons who represented to us that they are accredited investors as defined in Rule 501 of Regulation D promulgated under the Securities Act and acquiring the securities for investment, for their own account, and not for resale or with a view to distribution thereof in violation of the Securities Act, and the rules and regulations promulgated thereunder.

On June 24, 2014, we issued unregistered securities pursuant to the Mayne Purchase Agreement and the HPLLC Agreement. For a detailed discussion of the securities issued pursuant to these purchase agreements, see "CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS."

On June 24, 2014 as a condition to the Mayne Purchase Agreement, we entered into a Securities Purchase Agreement with Hedgepath, LLC. Pursuant to such agreement, Hedgepath, LLC purchased 20,000,000 shares of our common stock at a purchase price of $0.075 per share for an aggregate purchase price of $1,500,000. Such purchase price is payable as follows: (i) an advance payment of $125,000 made by Hedgepath, LLC on June 4, 2014 was deemed partial funding of the purchase price; (ii) a payment of $125,000 was made by Hedgepath, LLC on June 24, 2014; and (iii) the remaining $1,250,000 will be funded in monthly installments through December 31, 2014 pursuant to a promissory note issued by Hedgepath, LLC to us. Pursuant to the note, commencing on June 30, 2014 and ending on December 31, 2014, Hedgepath, LLC must make monthly payments to us in accordance with the terms and conditions of the note. We have the right, in our sole discretion, to request an advance payment of part or all of the principal of the note. The note bears no interest except upon an event of default in which case interest accrues at 18% per annum. In the event that Hedgepath, LLC defaults on part or all of the note, we have the right to declare by written notice that Hedgepath, LLC forfeit some or all of the 20,000,000 shares of common stock purchased as well as 17,646.98 shares of Series A Preferred Stock (or the common stock equivalent upon conversion thereof) held by Hedgepath, LLC. Such securities were issued in a transaction exempt from the registration requirements under Section 4(a)(2) and/or Regulation D of the Securities Act inasmuch as they were issued to less than ten sophisticated persons who represented to us that they are accredited investors as defined in Rule 501 of Regulation D promulgated under the Securities Act and acquiring the securities for investment, for their own account, and not for resale or with a view to distribution thereof in violation of the Securities Act, and the rules and regulations promulgated thereunder.

On June 24, 2014, as a condition of closing of the Mayne Purchase Agreement, we entered into a Debt Forgiveness Agreement with Hedgepath, LLC pursuant to which Hedgepath, LLC waived, canceled and forgave payment from us of an aggregate of $639,767 of indebtedness previously advanced by Hedgepath, LLC to us in exchange for 2,530,227 shares of common stock, 71,635.981 shares of Series A Preferred Stock and a warrant to purchase 10,250,569 shares of common stock. The shares of Series A Preferred Stock converted into 82,156,842 shares of common stock on August 14, 2014. The warrant may be exercised by Hedgepath, LLC at an exercise price of $0.0878 per share at any time, from time to time, by Hedgepath, LLC prior to expiration on June 24, 2019. The issuances contemplated by the Debt Forgiveness Agreement are exempt from registration pursuant to Section 4(a)(2) and/or 3(a)(9) of the Securities Act.

On June 24, 2014, in fulfillment of one of the conditions under the Supply and License Agreement, we entered into the Mayne Purchase Agreement. Pursuant to the terms of the Mayne Purchase Agreement, we issued to Mayne Pharma (i) 258,363.280 shares of our Series A Preferred Stock, and (ii) a warrant to purchase 10,250,569 shares of our common stock. The shares of Series A Preferred Stock converted into 87,843,897 shares of common stock on August 14, 2014. The warrant has an exercise price of $0.0878 per share and may be exercised at any time, from time to time, by Mayne Pharma prior to the expiration on June 24, 2019. As a result of the Mayne Purchase Agreement, Mayne Pharma owns approximately 40% of our equity securities on a fully diluted basis. Such securities were issued in a transaction exempt from the registration requirements under Section 4(a)(2) and/or Regulation D of the Securities Act inasmuch as they were issued to less than ten sophisticated persons who represented to us that they are accredited investors as defined in Rule 501 of Regulation D promulgated under the Securities Act and acquiring the securities for investment, for their own account, and not for resale or with a view to distribution thereof in violation of the Securities Act, and the rules and regulations promulgated thereunder.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibit No.	Description
2.1	Agreement and Plan of Merger and Reorganization, dated as of August 9, 2013, between Commonwealth Biotechnologies, Inc., and the Company (1)
3.1	Certificate of Incorporation of the Company (1)
3.2	Amended and Restated Bylaws of the Company(2)

3.3	Certificate of Ownership and Merger relating to merger of Commonwealth Biotechnologies, Inc., and the Company (1)
4.1	Warrant, dated June 24, 2014 issued to Mayne Pharma Ventures Pty Ltd. (3)
4.2	Warrant, dated June 24, 2014 issued to Hedgepath, LLC (3)
4.3	Form of Placement Agent Warrant (**)
5.1	Opinion of Ellenoff Grossman & Schole LLP(**)
10.1	Contribution Agreement, dated August 13, 2013, by and between Hedgepath, LLC, and the Company (1)
10.2	Securities Purchase Agreement, dated June 24, 2014, by and between the Company and Mayne Pharma Ventures Pty Ltd. (3)
10.3	Stock Purchase Agreement, dated June 24, 2014, by and between HedgePath Pharmaceuticals, Inc. and Hedgepath, LLC (3)
10.4	Promissory Note, dated June 24, 2014, issued to the Company by Hedgepath, LLC (3)
10.5	Equity Holders Agreement, dated June 24, 2014, by and between the Company, Mayne Pharma Ventures Pty Ltd., Hedgepath, LLC, Nicholas J. Virca and Frank O'Donnell, Jr. M.D. (3)+
10.6	Debt Forgiveness Agreement, dated June 24, 2014, by and between the Company and Hedgepath, LLC (3)
10.7	Employment Agreement, dated June 24, 2014, between the Company and Nicholas J. Virca (3)+
10.8	Executive Chairman Agreement, dated June 24, 2014, between the Company and Frank O'Donnell, Jr. M.D. (3)
10.9	Amended and Restated Supply and License Agreement, dated June 24, 2014, by and among the Company and Mayne Pharma. (3)+
10.10	Employment Agreement, dated September 4, 2014, between the Company and Garrison J. Hasara (4)
10.11	Form of Securities Purchase Agreement (**)
23.1	Consent of Cherry Bekaert LLP(*)
23.2	Consent of PBMares, LLP(*)
23.3	Consent of Ellenoff Grossman & Schole LLP (contained in Exhibit 5.1) (**)
24.1	Power of Attorney (contained on signature page of this Registration Statement) (*)
101.ins	XBRL Instance Document(**)
101.xsd	XBRL Taxonomy Extension Schema Document(**)
101.cal	XBRL Taxonomy Calculation Linkbase Document(**)
101.def	XBRL Taxonomy Definition Linkbase Document(**)
101.lab	XBRL Taxonomy Label Linkbase Document(**)
101.pre	XBRL Taxonomy Presentation Linkbase Document(**)

* Filed herewith.
** To be filed by amendment.
\+ Confidential treatment has been granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.
(1) Previously filed with Form 8-K, dated August 16, 2013.
(2) Previously filed with Form 8-K, dated July 24, 2014.
(3) Previously filed with Form 8-K, dated June 30, 2014.
(4) Previously filed with Form 8-K, dated September 9, 2014.

ITEM 17. UNDERTAKINGS

The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

    a. To include any prospectus required by Section 10(a)(3) of the Securities Act;

    b. To reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in the volume and rise represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

c. To include any material information with respect to the plan of distribution not previously disclosed in this Registration Statement or any material changes to such information in the Registration Statement.

2. For determining liability under the Securities Act, treat each post-effective amendment as a new registration statement of the securities offered, and the offering of the securities at that time to be the initial bona fide offering.

3. To file a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.

4. For determining liability of the undersigned issuer under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned issuer undertakes that in a primary offering of securities of the undersigned issuer pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned issuer will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

i. Any preliminary prospectus or prospectus of the undersigned issuer relating to the offering required to be filed pursuant to Rule 424;

ii. Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned issuer or used or referred to by the undersigned issuer;

iii. The portion of any other free writing prospectus relating to the offering containing material information about the undersigned issuer or its securities provided by or on behalf of the undersigned issuer; and

iv. Any other communication that is an offer in the offering made by the undersigned issuer to the purchaser.

5. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer of controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

6. For determining any liability under the Securities Act, treat the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant under Rule 424(b)(1) or (4) or 497(h) under the Securities Act as part of this registration statement as of the time the Commission declared it effective.

7. For determining any liability under the Securities Act, treat each post-effective amendment that contains a form of prospectus as a new registration statement for the securities offered in the registration statement, and that offering of the securities at that time as the initial bona fide offering of those securities.

8. That, for the purpose of determining liability under the Securities Act to any purchaser:

a. If the issuer is relying on Rule 430B:

1. Each prospectus filed by the undersigned issuer pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

2. Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

b. If the issuer is subject to Rule 430C:

Each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Tampa, State of Florida, on September 17, 2014.

HEDGEPATH PHARMACEUTICALS, INC.

/s/ Nicholas J. Virca
Name: Nicholas J. Virca
Title: President and Chief Executive Officer
(Principal Executive Officer)

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Nicholas J. Virca and Garrison J. Hasara, and each of them, as true and lawful attorneys-in-fact and agents with full power of substitution and re-substitution and for him and in his name, place and stead, in any and all capacities to sign any and all amendments (including pre-effective and post-effective amendments) to this Registration Statement, as well as any new registration statement filed to register additional securities pursuant to Rule 462(b) under the Securities Act, and to file the same with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Nicholas J. Virca Nicholas J. Virca	President and Chief Executive Officer (Principal Executive Officer)	September 17, 2014
/s/ Garrison J. Hasara Garrison J. Hasara	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	September 17, 2014
/s/ Frank E. O'Donnell, Jr., M.D. Frank E. O'Donnell, Jr., M.D.	Executive Chairman and Director	September 17, 2014
/s/ Samuel P. Sears, Jr. Samuel P. Sears, Jr.	Director	September 17, 2014
/s/ W. Mark Watson W. Mark Watson	Director	September 17, 2014
/s/ Stefan J. Cross Stefan J. Cross	Director	September 17, 2014
/s/ R. Dana Ono Dr. R. Dana Ono	Director	September 17, 2014

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference of our firm under the caption “Experts” in this Registration Statement on Form S-1 and related prospectuses of Hedgepath Pharmaceuticals, Inc. dated September 12, 2014 and to the inclusion therein of our report, dated April 15, 2014, with respect to the financial statements of HedgePath Pharmaceuticals, Inc. included in its Form 10-K filed April 15, 2014 with the Securities and Exchange Commission.

/s/ CHERRY BEKAERT LLP

Tampa, Florida
September 17, 2014

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Registration Statement on Form S-1 of HedgePath Pharmaceuticals, Inc., as successor to Commonwealth Biotechnologies, Inc. of our report dated May 13, 2013 relating to our audit of the financial statements, appearing in the prospectus, which is part of this Registration Statement.

/s/ PBMares, LLP

Richmond, Virginia
September 17, 2014